

DRUG INDUSTRY AND THE INDIAN PEOPLE

Edited by
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**DELHI SCIENCE FORUM
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and

**FEDERATION OF MEDICAL REPRESENTATIVES
ASSOCIATIONS OF INDIA
PATNA**

Drug Industry and The Indian People

Proceedings and papers presented at the 'All India Seminar
on National Drug Policy' held in New Delhi
on 28th and 29th April 1986.

Edited by
Dr. Amit Sen Gupta

Foreword by
Shri P. N. Haksar

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publication.

to protect their narrow respective interests. Unfortunately, the public interests who have a major stake in the national drug policy and should be heard carefully, have not been taken into confidence at all. This is partly also because they are not as well organized as the industry is.

With this fact in mind that the opinion of those who have a major stake would have to be galvanized if the policy is to be influenced in favour of certain definite objectives like introduction of production and price controls to achieve essential drug production at affordable prices, re-defining the aims of drug and quality control mechanisms to ensure ethical marketing and a rational drug information system for health personnel and consumers and creation of a suitable licensing and technology acquisition system to ensure self-reliance in drug production.

The seminar was attended by over hundred people. Representatives of Indian Medical Association, Medical Representatives, Scientists, Government S&T organizations, N. G. O.s involved in health care, People's Science Movements, Trade Unions, Women's organizations and a retired judge, were present in the discussions at the seminar. As organizers, we were immensely gratified by the enthusiasm with which the idea of the seminar was received. As a follow-up measure, people in Andhra Pradesh and Madhya Pradesh have already held conventions calling more participants from within their States. The Pondicherry Science Forum has followed the seminar up with a booklet on the issues discussed at the seminar which has been widely circulated. The whole idea, as expected, is taking the shape of a movement for a rational drug policy geared to the objectives of essential drug production at reasonable prices and self-reliance.

The comments and the discussions were particularly incisive and fruitful. Several of the authors have revised their original papers substantially for this volume on the basis of the comments they received from the participants. We are extremely grateful to the contributors and the participants for the interest they took in this seminar on national drug policy.

We are also grateful to all those persons who gave us unstinted support in the organization of the seminar and the publication of this volume. It is our hope that the papers printed in this volume will generate serious debate and influence positively the movement for the achievement of a rational drug policy.

Like everyone else, poor Indian people want an effective and affordable solution to their health problems. Cheap and quick relief is an economic necessity of the poor people. Loss of a working day can add to the misery and even bring disaster if the disease persists for a few days longer than they can really afford. It is for this economic reason that drugs and curative medicines which otherwise constitute only a small part of the overall health care system, become the most urgent, essential and hence a priority need for our country. This will remain so as long as the basic

elements of health care such as food, shelter, healthy and safe environment are not made available universally to all the Indian people.

However, the irony of the present situation is that the drug manufacturers in India are not oriented towards meeting the needs of the people, but in devising ways and means of earning profit. They are busy pushing all sorts of irrational and inessential drugs down the throats of the consumers. The poor are encouraged to buy vitamins, tonics, cough mixtures, cold-killers and hundreds of similar products both directly through advertisements in the media, and at point of sales by Pharmacists and also through prescriptions issued by Doctors. Drugs are being marketed without proper information and adequate consumer alerts which can do more harm than good. The drug control mechanisms of the government have not kept pace with the demands made by the rational therapeutics and the growth of the drug industry.

Most of the important policy instruments concerning the pricing and production of drugs proposed in the 1978 drug policy till date remain unimplemented. Even thirty-nine years after Independence, multinational corporations continue to dominate the drug industry in India. I hope that this volume will make some contribution towards evolution of a sensible as well as sensitive drug policy in our country.

New Delhi
December 10, 1986

P. N. HAKSAR
President
Delhi Science Forum

Proceedings of All India Seminar on National Drug Policy

An All India Seminar on National Drug Policy was held in New Delhi on 28th and 29th April, 1986. Earlier, an organising committee consisting of Mr. P. N. Haksar (Chairman), Dr. N. P. Gupta (Deputy Chairman), Dr. S. K. Goyal, Mr. K. Ashok Rao, Dr. Sujata Dhawale, Dr. B. Ekbal, Dr. H. Aggarwal, Mr. J. S. Majumdar (Convenor) and Mr. H. S. Paul (Treasurer) had been constituted for this purpose.

In the inaugural session, Mr. J. S. Majumdar introduced the Seminar and outlined the objectives. Dr. N. P. Gupta in his welcome address said that the Seminar was a small step in realising the goal of a truly people-oriented National Drug Policy. He expressed the hope that this beginning shall develop into a big movement throughout the country.

Dr. Nityanand (Former Director, CDRI, Lucknow) put forward his views on the state of the Drug Industry. He said that a paradoxical situation existed, where though the Industry had grown tremendously over the years, essential drugs were always in short supply. The Industry, he said, could not grow on the desired lines if it continued to cater to only 20 per cent of the population who were in a position to buy medicines. He emphasised the role of the National Sector in promoting self-reliance in the drug industry. He expressed concern that recent policy pronouncements did not augur well for the growth of a self-reliant industry. He said that adequate production of essential drugs, development of self-reliance and sustained R&D efforts were the key areas which had to be tackled on a priority basis.

Dr. V. Paramesvara (President, Indian Medical Association) expressed the IMA's support for the Seminar's objective of attempting to evolve a rational Drug Policy for the country. He said that the IMA had been raising the related issues in many of its forums.

The inaugural session was followed by sessions covering the areas of Health and Diseases; Drug Requirements; Drug Production and Pricing; Drug Distribution, Marketing and Information; Self Reliance and Legislation; and Policy matters. A selection of the papers presented at these sessions is reproduced in the following pages.

Mr. J. S. Majumdar moved a resolution (reproduced in this book) on behalf of the Organising Committee, in the concluding session. After a

lively and fruitful discussion, it was adopted unanimously but for a note of dissent on one point by Mr. Atul Dutta (General Secretary, AIOCD). Mr. Dutta objected to the call for Nationalisation of the Drug Trade, in the absence of a call for the Nationalisation of the Drug Industry.

RESOLUTION

Resolution adopted in the All India Seminar on National Drug Policy held at New Delhi on 28th and 29th April, 1986 and attended by 131 delegates representing various scientific and educational institutions, Indian Medical Association and other organisations of medical practitioners; All India Association of Chemists and Druggists; Central Trade Unions; Industrial Federation of the Workers; Organisations of Women, Youth and Students; eminent scientists and economists; retired judge of Supreme Court; organisations of workers and officers in the drug industry, including medical and sales representatives; scientists' organisations; and Members of Parliament.

The Seminar,

having discussed the various aspects of existing Drug Policy;

noting with concern that hitherto the Drug Policy was oriented for trade and industrial development, utterly neglecting the actual health requirements of the people;

realising the need for an immediate change in the existing situation of health; production and supply of drugs to fulfil the needs of the people;

further realising the need for extensive public debate of the new Drug Policy, which is being formulated by the Central Government, involving the representatives of various sections of the people;

I. *Demands*, that the Central Government should announce the new Drug Policy as a draft document for discussion by various sections of the people and their organisations to offer their specific suggestions and comments.

II. *Recommends*,

1. Whereas, today there is total lack of social control and public accountability of the drug industry;

the Government should constitute a National Drugs and Therapeutics Authority (NDTA), having representatives from drug and health authorities of the Central and State Governments, trade unions related to drug industry, medical profession, chemists and druggists, various scientific organisations and experts; and which should have statutory powers to implement the provisions of the National Drug Policy.

should be provided under Drugs and Cosmetics Act, 1940;
the Drug Control authorities of the Governments shall be responsible for supply of certified quality drugs by the manufacturers.

9. Whereas, a large quantity of spurious drugs are being manufactured and sold by the anti-socials throughout the country;
the Government should amend the Indian Penal Code and ensure vigilance by the police authorities assisted by the drug control authorities to stop this menace.
10. Whereas, liberal import of bulk drugs and drug intermediates under OGL has resulted in affecting indigenous production both in public as well as private sectors;
the Government should cannalise all drugs and drug intermediates and basic chemicals and remove drugs from the list of OGL;
the Government should stop import of such bulk drugs where drug equivalents in the same therapeutic group are available within the country.
11. Whereas, delicensing and DGTD registration of ex-FERA companies have caused immense harm to the development of national sector of drug industry;
the Government should cancel the scheme of delicensing and DGTD registration for the ex-FERA companies and cancellation of all their unimplemented capacities in the drug industry without any delay;
the Government should encourage and support the Indian Private Sector in drug industry, mostly consisting of the middle and small scale sector companies with sectoral reservation and other incentives for the production and supply of essential drugs of high standard of quality from their basic stages at low price to complement the public sector efforts.
12. Whereas, research should be guided by the health needs of the Indian people to combat communicable and other diseases causing greater mortality and morbidity in different parts of the country;
whereas, research should be aimed at manufacturing of preventive medicines like vaccines and curative drugs of essential value;
whereas, research should be aimed at development of indigenous technology;
whereas, import liberalisation, delicensing, etc., are acting as hindrance in the indigenous R&D efforts;

the Government, instead of tax concessions, should provide research grants for R&D, aiming at achieving the above mentioned objectives;

the Government should give adequate protection to the development of new drugs being developed in India both by public and private sectors.

13. Whereas, the brand names of drug industry are an irrational source of market power which have resulted in high prices of drugs and irrational drug formulations in Indian market;
whereas, the Hathi Committee recommended abolition of brand names in stages with 13 single ingredient bulk drug formulations for immediate implementation; whereas, 1978 drug policy abolished brand names from five single ingredient bulk drug formulations but failed to implement the same due to legal flaw in implementation;
the Government should abolish the brand names from drug formulations and use generic names in their place and take appropriate steps under law for their implementation.
14. Whereas, increasing pressure is being built by the foreign and vested interests on the Indian Government to join the Paris Convention of Patent Protection against the country's interests for self reliance and which, if joined, would be a retrograde step from Indian Patent Act, 1970;
the Government of India should not join the Paris Convention on Patent Protection;
further, the Government should take steps for removal of patent rights on drugs.
15. Whereas, the burdens on consumers are increasing due to increasing prices of drugs, the industry is campaigning for upward revision of drug pricing scheme based on the studies financed by the industry (like the study done by NCAER and financed by OPPI) and which are being used as the basis in support of claim for price revision;
the Government should ensure an independent cost study to be done by BICP before any alteration in the mark-ups in 1978 Drug Policy and Drug (Price Control) Order, 1979, which should be made public.
16. Whereas, one of the contributory factors for the high prices of drugs is the excise duty on drugs collected at various stages;
the Government should remove excise duty on all essential drugs to provide immediate relief to the people.

17. Whereas, in the distribution of drugs, the manufacturers introduce a number of middlemen like C & F agencies, super stockists, etc., resulting in price increase of drugs and affecting the supply of essential drugs in spite of market demands;
to streamline the distribution channel of drug supply and to ensure the supply of this essential commodity;
the Government should establish a Central drug procurement and distributing agency as recommended by UNIDO for the supply of drugs to the hospitals, dispensaries, primary health centres and to wholesale and retail chemists in the market.
18. Whereas, many important provisions of the drug policy remain unimplemented like DPCO, 1979, like banned drugs through Gazette Notification, like introduction of generic names of the drugs due to stay orders obtained by the industry using the legal flaw in implementing the decisions;
the Government should bring appropriate changes in the existing drug laws to ensure that all the provisions in the drug policy can be implemented unhindered;
the Government should introduce a pharmaceutical code to tackle the offences of the drug manufacturers, their agents and distributors;
the Government should establish special tribunals for drug industry to tackle their offences under law.
- III. *Appeals*, to all sections of the people of India, who are concerned with the fulfilment of democratic aspirations of the people in respect of real health and drug needs, to pursue these conclusions and recommendations of this Seminar at the broadest possible level for developing a democratic movement. □

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Background Paper

*J. S. Majumdar **

Introduction

The Government of India has, for some time, been wanting to introduce a New Drug Policy in the Parliament. For this purpose the National Drug and Pharmaceuticals Development Council (NDPDC) in its first meeting in May 1983 recommended the formation of three Working Groups to study and report to the Council on the various aspects of the existing drug policy, the need for review or revision of the existing policy and to recommend changes wherever necessary.¹ The reports of the Working Groups were submitted in January-February 1984. NDPDC constituted a Steering Committee in March 1984 to consolidate these reports and finalise its recommendations. The Steering Committee submitted the report and recommendations to the Minister for Chemicals in August 1984. The Government informed the Parliament that a new Drug Policy would be introduced soon and for that purpose recommendations of NDPDC had been received.

On 3 January, 1986 the Minister of State for Chemicals & Petrochemicals informed in a Press Conference that a new Drug Policy, which would be introduced soon, would do away with all the 'unworkable' provisions of the existing policy and those of the Drug Price Control Order of 1979. The Policy would be in line with the Government's liberalised industrial policies; there would be no separate provisions in the Policy for the national sector. He also informed that some of the provisions of the existing policy and the Drug Price Control Order, 1979 — like unintended profits by drug companies, Drug Price Equalisation Fund, and fixing of prices — could not be implemented by the Government, therefore, the intention of the new policy would be to remove these 'unnecessary' and unworkable provisions.²

On 6 February 1986, six organisations in a meeting in New Delhi came to the consensus that all aspects of the existing drug policy had not been

* Mr. J. S. Majumdar is the General Secretary of the Federation of Medical Representatives' Association of India. Both Mr. Majumdar and his organisation have, for long, been campaigning against the unethical and unscientific practices of the Drug companies.

of pharmaceuticals, a UNIDO study has revealed. Tropical diseases are big killers in tropical countries, but the study revealed that in the six countries surveyed, anti-parasitic drugs account for only 1 to 2 per cent of the total drugs consumed.⁶

From these reports a disturbing picture emerges. A country like India, which spends only 1 per cent of GNP for health care expenditure, spends about 50 per cent out of it for pharmaceuticals while only a small portion is spent for eradication and control of parasitic diseases.

Essential and Non-Essential Drugs

Pharmaceuticals cannot be considered in isolation from the health care system. Yet the production and usage pattern of pharmaceuticals in India do not confirm this.

Although medicinal products constitute essential tools for health care, it is observed that Drug Policies are often directed towards industrial and trade development⁷. Because of this distorted objective, the Drug Policy in India is formulated by the Department of Chemicals and Petro-Chemicals under the Industry Ministry and not by the Health Ministry.

Consequences are disastrous for the country. Essential drugs constituted only 16.8 per cent of the total drugs consumed in the country in 1980. Not only that, the production and usage of essential drugs, which are grouped in categories I and II in 1978 Drug Policy, dropped by 4.4 per cent during 1978 to 1980.⁸ (*Appendix-2 and 3*).

It is more disturbing that the industry, being completely insensitive to the actual needs of the ailing masses, have pushed up production, promotion and usage of non-essential pharmaceuticals and nutritive supplements. A host of pharmaceutical products are produced and promoted with the claim of correcting situations arising out of under-nourishment and malnutrition. Nutritional deficiency arising out of poverty and ignorance is sought to be corrected by costly pre-digested protein food, Anabolic Steroids, Iron, Haemoglobin, Glycerophosphates, Calcium, Vitamins and Malt Tonics. Even the appetite stimulating side-effect of an anti-histamine drug is made use of to promote the drug as a 'Tonic'.

In diarrhoea, which claims 50 per cent of deaths in children, useless pharmaceuticals are promoted to check dehydration. When WHO came out with a simple formula combining salt, sugar, Potassium and Sodium bicarbonate for the management of diarrhoea, a number of drug firms flooded the market with costly preparations claiming the added advantage of taste and flavour.

The industry has contributed hardly anything in the area of preventive medicines. That is why Hathi Committee commented, "the firms have reduced life to disease, to be cured in those countries by their sales propaganda technique."⁹

WHO observed, 'Resources are often wasted in purchasing expensive drugs that are only marginally useful or even irrelevant to the solution of a country's health needs, where large segments of the population are in urgent need of essential drugs for disease control and primary health care.'¹⁰

Being concerned with such proliferation of non-essential drugs at the expense of life-saving and essential drugs, WHO took the initiative and constituted an Expert committee on Selection of Essential Drugs. WHO prepared a model list of 200 drugs and advised the member countries to prepare their own Essential Drugs List as per each country's requirements, selecting drugs from the model list based on the criteria of selection decided by the Expert Committee. (*Appendix-4*)

In India also efforts were made to prepare an Essential Drugs List with the main objective of price control, with the misconceived notion that by controlling the prices of essential drugs, these would be available at reduced prices to all. Simultaneous efforts were not made to ensure production of these price-controlled essential drugs and check the proliferation of non-essential drugs and nutritive supplements.

A list of 17 essential drugs was prepared in 1967 by the Committee on Essential Drugs. Tariff Commission in their Report in 1968 studied the cost structures of these 17 essential bulk drugs and their formulations and made recommendations aimed at bringing down the prices of essential drugs, curbing excessive profits, promoting R & D and diversification of future development of this industry etc.¹¹ (*Appendix-5*)

Hathi Committee considered this list of essential drugs, sought opinion of experts, and prepared a list of Essential Drugs consisting of 104 bulk drugs. (*Appendix-6*)

Drug Policy, 1978 prepared a list of 37 bulk drugs grouped in category I & II formulations which are 'highly essential and life-saving'. It is interesting to note that the Drug Policy 1978 attempted to make a graded list of essential bulk drugs on their essentiality even though it ended only in adopting the measures of price control (*Appendix-7*)

The Steering Committee of NDPDC shifted from the 'Essential Drug List' and prepared 'Priority List' of 95 drugs. (*Appendix-8*)

The Government has not yet explained the criteria on which the list of priority drugs was prepared. Is it the demand in the market or hospitals or private clinics that will determine selection in the list of Priority Drugs? In our opinion a proper assessment of the requirements of the national programmes of eradication and control of communicable diseases should be taken as the basic determinant for preparing the list.

Nor have the benefit/risk ratio of the various drugs, the cost factor, availability of indigenous technology and raw materials and production facilities been weighed properly in preparing the list of priority drugs.

Examination of a few items in the list reveals certain disturbing facts. The Government stated that the shortage of anti-T. B. drugs like PAS and INH was due to 'demand constraints or shifts'.¹² A survey in the market reveals that the producers stopped supplying these essential drugs in spite of their high demands and there was actually no demand shifts. (Appendix 9). Drug Policy 1978 enlisted INH and PAS in category I group of drugs and Rifampicin and Pyrazinamide in category III. While technology, raw materials and manufacturing facilities are available indigenously for INH and PAS, those for Rifampicin and Pyrazinamide are not available indigenously. The cost factor for Rifampicin and Pyrazinamide is high. Benefit/risk ratios of these two groups of drugs have not yet been properly evaluated. Rs. 15.85 crores worth of bulk Rifampicin were imported during the year 1983-84.¹³ Yet the Priority List of drugs includes both Pyrazinamide and Rifampicin.

Banned and Hazardous Drugs

In addition to the problem of inadequate supply of essential drugs and proliferation of non-essential and irrational pharmaceutical products, the problem of hazardous effect of drugs has not been properly recognised. A number of studies, reports and articles have been published on this aspect in India and in different parts of the world. Unfortunately, adequate provisions are lacking in the drug policy to prevent the production, promotion and sale of these hazardous drugs.

It is a well known fact that the transnational drug firms manufacture, promote and sell hazardous drugs in the Third World countries including India which are either banned or are not in use singly or in combination in their countries of origin.

Another aspect has also started coming to light. Drugs are marketed for certain indications in the Third World countries, though the same indications are not used to market these drugs in the developed countries.

Unfortunately the existing drug policy, contains no provision by which manufacturers can be restrained from such practices.

The situation has become all the more alarming on account of the policy of the U. S. Government after the 1978 amendment of the U. S. Foods and Drugs Act which permits the export of pharmaceuticals that have been tested only on animals.¹⁴

Recently the Senate Sub-Committee of the United States passed a Bill that would permit export of drugs which are not approved by the F.D.A. The laws of E.E.C. countries also do not prevent export of hazardous drugs banned in their countries.

Information concerning the banning of drugs are regularly received by the Government through WHO. But the Government has failed to take

adequate measures to review such hazardous drugs on a priority basis.

When serious concern was expressed inside and outside the Parliament, the Government took steps to ban the production and sale of certain drugs. The Drug Technical Advisory Board recommended banning of 18 fixed dose combinations, and accordingly the Drug Controller (India) issued notification banning manufacture from 30 September 1982 and sale from 1 April 1983 of such combinations.

The order of Drug Controller (India) was stayed by Bombay High Court on the application of Retail and Dispensing Chemists Association of Bombay. The Court ordered that the notification under sec. 26(A) of the Drugs and Cosmetics Act with a list of formulations should be published in the gazette.¹⁵

Another company, Boehringer Knoll challenged the Government's order and got an interim stay from Bombay High Court restraining the Drug Controller to give effect to this notification.

Similarly, on 13 June 1982, Drug Controller (India) issued a notice banning production from 31 December 1982 and sale from 30 June 1983 of Oestrogen-Progesterone combination drugs. The order was challenged by Organon, Ciba-Geigy and Unichem and they obtained stay orders from Calcutta and Bombay High Courts.

The Ministry of Health and Family Welfare issued a notification on 23 July 1983 banning 25 drug preparations. (*Appendix-10*)

Due to the High Courts' orders and certain legal lacunae, the Government could not implement its own decision. As a result, such banned drugs are still being manufactured, promoted and sold in the country.

The Government is yet to suggest any provision by which it can take effective steps to protect the ailing people of India from the effect of hazardous drugs, if necessary by amending the drug laws appropriately.

Development and Structure of the Industry

At the beginning of this century, Acharya P. C. Ray and Professor T. K. Gajjar were the pioneers in establishing the pharmaceutical industry in India. The First World War gave a stimulus to indigenous production due to import restrictions mainly of sera, vaccines and anti-malarial drugs. Bengal became the main centre of the pharmaceutical industry. Before the Second World War there was enthusiasm for indigenous research and process development independent of foreign help. During this period the discovery of Urea Stibamine and research efforts with *Raulfia Serpentina* were some of the significant contributions made by the Indian scientists for the development of modern medicines. The process development for the manufacture of Iodochlorhydroxyquinoline, many alkaloids, chemotherapeutic agents, colloidal preparations, apart from process development

in the production of sera and vaccines are all contributions of the national sector of the drug industry in the pre-independence period. The process development for the manufacture of Penicillin by Dr. Ghosh in West Bengal was a landmark in indigenous technological development. During the pre-independence period, like in many other fields, a sense of nationalism developed in advancing the Indian pharmaceutical industry, independent of foreign tie-ups.

Side by side, some multinational companies, mostly of British origin, were engaged in importing finished formulations in package form from their principal companies. At the time of independence the total pharmaceuticals sale was estimated to be Rs. 10 crores.

Immediately after independence the Government of India made its Industrial Policy Statement in 1948. This policy decision envisaged that for capital formation and for industrialisation :

- "No discrimination would be made between foreign and Indian undertakings in the application of general industrial policy".
- "Reasonable facilities, consistent with foreign exchange position would be given for the remittance of profits".
- "In case of nationalisation, fair and equitable compensation would be paid".

This policy decision of the Government opened the floodgate for the entry of the multinational drug firms in India. But, the hope that the companies would help in capital formation and help in formation of an industrial base through their modern technology were proved to be wrong within the next few years. As the Hathi Committee report pointed out, shortly after independence most of the leading multinational drug companies established themselves as trading concerns. The initial investments were also insignificant. They started by importing finished drug formulations and marketing them. Subsequently, they started importing bulk formulations and got them packed in this country. (Appendix-11)

Therefore, neither did India obtain technology to form an industrial base for the production of bulk drugs from the basic stage, nor was capital formed through foreign investments. On the contrary, within one year's time, during 1951-52, India had to import Rs. 15.6 crores worth of medicines. Huge amounts were being remitted every year out of this country in the name of royalty rights. According to the Reserve Bank of India Bulletin of November 1964, these MNCs had since 1958 invested Rs. 5 crores and had by 1964 already taken out of the country Rs. 4.9 crores in foreign exchange in the form of royalties, charge of technical aids and profits.

On the other side, the national sector of the industry could not stand up in the face of aggressive marketing practices of the MNCs and the import

of newer medicaments. The tempo of the national sector to pursue an independent line of industrial development was lost.

The multinational companies developed an intricate system of business partnership with traders and distributors, which also prompted the Indian industrialists to tie up with these foreign companies for quick returns. This relationship was firmly established by the formation of Pharmaceutical and Allied Manufacturers and Distributors Association Ltd. (PAMDAL), which became the main spokesman to protect the interests of the multinationals in the drug industry in this country.

This was the period when the multinational drug firms of US origin tremendously over-priced their antibiotics supplied to India. The Kefauver Committee of United States Senate noted, "The prices in India for the broad-spectrum antibiotics, Aureomycin and Achromycin, are among the highest in the world. As a matter of fact, in drugs generally India ranks among the highest priced nations of the world, a case of an inverse relationship between per capita income and the level of drug prices".

When multinational drug firms did not provide technological base, the Hindustan Antibiotics Ltd. was established with technological assistance of WHO and UNICEF in 1954.

The 1956 Industrial Policy Resolution set the tempo of industrialisation with emphasis on self-reliance. It envisaged a leading role for the public sector. In 1956-57, the Soviet Union offered free technical assistance for development of a fully integrated drug industry in the public sector. But an agreement in this regard was delayed.

A leading American technical journal, Chemical and Engineering News (November 24, 1958, page 73) reported, "Merck's entry in Indian pharmaceutical makes friends, future profits and helps sideswipe Soviets

"Merck's efforts have helped in part to stall the Soviet offensive; however, Knoppers fully admits that eventually some products in this area will be produced using Russian knowledge and aid. But the original Soviet offer, which was all embracing (and somewhat obsolete, technologically, some say), is shelved, and the Indian Pharmaceutical industry will not be a government monopoly."¹⁶

Hence, Hindustan Antibiotics Ltd. entered with technological tie-up with Merck & Co. of USA for Streptomycin production and American Home Product for Ampicillin production.¹⁷

In 1961 IDPL was established with assistance from the USSR in a much reduced form than originally planned. Its plants i.e., Antibiotics Plant at Rishikesh and Synthetic Drugs Plant at Hyderabad started commercial production in 1967-68 by stages and the Surgical Instruments Plant started production in 1965.

Efforts to make the country self-reliant in production of drugs, mainly through the public sector, triggered off a new situation. Out of fear of

losing a lucrative market, multinational companies started establishing factories in collaboration with their partners or converted their trading houses as subsidiaries. But even at this time they did not contribute much towards production of pharmaceuticals from basic stages. The Committee on Drugs and Pharmaceuticals Industry (popularly known as Hathi Committee) in their report in April 1975 revealed the *modus operandi* of these MNCs to operate through 'permission letters'. Various studies also revealed the high level of transfer pricing by the MNCs in drug industry particularly by importing costly intermediates from their parent organisations abroad. The MNCs were reluctant to manufacture pharmaceuticals from their basic stages.

These MNCs formed their own Association, Organisation of Pharmaceutical Producers of India (OPPI), which emerged as their spokesman, replacing PAMDAL.

By early seventies the traders, distributors and business associates of these MNCs started establishing their own firms, though mainly in the formulation area. Being closely associated with the MNCs, they learnt the art of marketing. Therefore, this newly emerging national private sector started imitating the marketing practices of these MNCs in drug industry and started challenging the monopoly control of multinationals in the drug market. The experiences gained by the technicians in the factories of multinationals also helped them immensely.

This national private sector followed a path which was distinctly different from the earlier efforts of the national sector for independent development of pharmaceutical industry on the basis of indigenous research and technology.

This national private sector, mostly in the small and middle scale sector, also started establishing factories for production of bulk drugs and intermediates in which the technological help from Hungary and other socialist countries was obtained.

This new national private sector formed their own association (IDMA), which became their main spokesman.

The lack of clear objective direction, bureaucratic control, mismanagement, and Government's policies as they were, relegated the public sector to a backward position. Efforts were made from time to time by the public sector to compete with the MNCs and the Indian private sector. They also started imitating the marketing practices of the MNCs. But the composition, structure and objectives of public sector can never allow them to adopt the same marketing practices as of a private sector company.

The Drug Policy 1978 helped the Indian private sector to make rapid progress due to restrictions on the multinationals, and protection to the Indian sector through sectorial reservation in respect of licensing, manufacture of bulk drugs and formulations etc.

This drug policy, having provisions for sectorial reservation and restriction on multinationals soon faced a massive campaign started by the multinationals. The Indian sector also started campaigning against the 1978 Drug Policy, which had helped them immensely, with the narrow perspective of price revision, and in the process helped the cause of the multinational sector to change the basis of the existing drug policy.

In this background, the MNCs got a real boost when the Government delicensed 94 bulk drugs, amended the Foreign Exchange Regulation Act (FERA) and Monopolies and Restrictive Trade Practices (MRTP) Act, and broad-banded drugs and drug-intermediates.

The struggle of the national private sector to stand up against the multinationals in the drug industry in India was revealed in the debate in Parliament on 'Salbutamol' licensing.

Regarding this debate Glaxo Laboratories lamented, "Parliament stands for the right of the people to be heard on issues involving national interests. Yet it is now being seen to be spending more of its time and attention on the causes of private parties who wish to further their own economic interests. Certainly, decision taken in respect to individual companies could, in certain instances, have relevance to national policy. But when Parliament is drawn into protracted wrangles in which individual interests appear to be the main consideration, it is not surprising that some of its own members are provoked to voice their protest against the manner in which proceedings are conducted. Again, when the Government, in arriving at its decisions, appears to apply the rules of national good to one party and waives those very rules for another, national policies lose their meaning altogether."¹⁸

This struggle was also revealed when the Minister for Chemicals and Fertilizers reported in the Parliament that formulation of the new drug policy was being delayed as, "Several lobbies of drug manufacturers" were working at cross purposes.¹⁹

While Glaxo Laboratories accuse the Parliament of serving vested interests, the Minister for Chemicals admits, in Parliament, "Violations like unauthorised imports of bulk drugs and intermediates, unauthorised production, excess production, unauthorised installation of plant and machinery, and marketing of items without price approval, alleged to have been committed by Glaxo Labs., have been brought to the notice of the Government."²⁰

By a majority decision, the Hathi Committee recommended nationalisation of all multinational drug firms. By another recommendation the Committee suggested immediate dilution of their foreign equity to 40 per cent and progressively reducing it further to 26 per cent.

Both these major recommendations of the Hathi Committee were ignored by the Government while formulating the 1978 Drug Policy. The

Pricing and Profitability

Drugs came under price control for the first time in 1962. The Drugs (Display of Price) Order, 1962 and the Drugs (Control of Prices) Order, 1963 were promulgated under the Defence of India Act, freezing prices of medicines as on 1 April, 1963.

Tariff Commission in their report of August 1968, after extensive study of the cost structure of 17 essential bulk drugs and their formulations, recommended bringing down their prices with a view to curbing excessive profits. Accordingly, Drugs Price Control Order, 1970 was issued under Essential Commodities act, 1955.

In addition to the 17 essential drugs, the costs of which were studied by Tariff Commission, the Bureau of Industrial Cost and Prices (BICP) examined the cost structure of bulk drugs and the prices of these drugs were fixed in 1974 on the basis of BICP recommendations.

Following the Drug Policy 1978, Drug (Price Control) Order, 1979 (DPCO 1979) was issued on 31 March, 1979.

According to DPCO 1979, for category I formulations, the ceiling on mark-up was fixed at 40 per cent and for category II formulations, at 55 per cent. As stated earlier, these two categories have been defined as life-saving and very essential drugs. For category III formulations, mark-up allowed was upto 100 per cent and for the rest of the formulations there was no price control.

NCAER study revealed that in 1980, category I had 3.6 per cent, category II 13.2 per cent, category III 68.6 per cent, and decontrolled formulations had 14.9 per cent of the market share.

For categories I and II formulations, DPCO 1979 provided for leader prices based on the most popular brand and putting a ceiling on the prices for all manufacturers for similar formulations. The prices, lower than the leader prices, were frozen and required approval for revision. For decontrolled group of drugs there are overall profitability ceilings. For category III formulations individual manufactures were to get approvals of their prices.

Under DPCO 1979 all corresponding bulk drugs of the price-controlled formulations were also brought under price control.

DPCO 1979 also provided Drug Equalisation Account and fixation of sales prices of imported bulk drugs, under which prior price approval was required. To protect the interests of indigenous manufacturers, fixation and retention of prices for individual manufacturers/importers and also for pooled prices for the sale of that bulk drug was required. Under this scheme the manufacturers/importers would pay into or take from Drug Equalisation Account the difference between retention prices and the pooled prices/common selling prices fixed under the order.

The National Council of Applied Economic Research (NCAER) published a report, 'The Indian Pharmaceutical Industry — Problems and Prospects' in January 1984. The report was based on a study sponsored by the OPPI.

The report of NCAER noted, "we have approached all the members of OPPI and selected members of IDMA for securing the above information. Repeated visits by the staff members of NCAER and appeals by the Secretariat of OPPI and IDMA did not help in evoking the desired degree of response. Data of formulation from 23 companies, based on which the trends in the ex-factory cost of formulations, expenses met out of mark-up, break-even mark-up and the mark-up actually enjoyed have been worked out. For purposes of analysing the cost price relations in bulk drugs we mainly depended on cost audit reports of 10 units, which formed the empirical basis for analysing the profitability trends in bulk drug production. *As the sample of companies furnishing the information is small, these may be treated as case studies, and no claim is made about its representativeness of the pharmaceutical industry.*" (Italics incorporated)

Two questions arise here. Why did the drug companies refuse to provide information pertaining to the costing of a drug? Even the NCAER study revealed that the drug companies were reluctant to provide these informations. In this regard Economic Times of 6 October, 1983 reports, "The Government had issued along with the order of Vitamin price revision in last August a detailed questionnaire seeking information pertaining to product-wise capital investment, profitability etc. in order to ascertain whether there is a case for any company for higher prices.

"Most of the drug companies making multivitamin formulations, however, declined to furnish such information to the Government mainly on the ground that time given for such an exercise is inadequate."

The second question arises as to the reliability of the NCAER report on cost study. The report itself clarified that it is not representative of the pharmaceutical industry. Further, the source of information of the NCAER study is some drug companies who are known to provide misleading information. To cite an example, in page 159 the report states, "A lower mark-up was considered adequate for categories I and II formulations since they, being mass consumption items, can be marketed with minimam promotional efforts. To verify the reasonableness of this hypothesis we requested the units to furnish selling and distribution expenses separately for each category of formulations manufactured by them. The units were unable to comply with this request due to the following reasons : The expenses met out of mark-up can be classified into two broad groups. Viz., (a) direct and (b) indirect. The direct costs, like trade commission and to some extent frieght can be related to the products or product groups. In the case of indirect costs, it is well nigh impossible to segregate costs attributable to different product categories. For instance sales force employed

promotes the entire range of products made by a unit. Similarly, costs incurred on maintenance of sales depots also come under this category." (Italics incorporated)

The claim that 'sales force employed, promotes the entire range of products made by a unit was not a correct information. Since DPCO 1979, sales force even in a single unit did not promote the range of products in categories I and II formulations. Similarly, the claim of maintenance of sales depot was also not correct as most of the drug units distribute their products through carrying and forwarding agency system and/or through distributor system.

It appears from the NCAER study, that the main basis on which the mark-ups in categories I and II formulations were fixed at 40 per cent and 55 percent (that is providing least expenses on sales promotional cost in these categories of formulations) was rejected on the misconceived notion that these categories of drugs also required promotional costs. As such, the break-even mark-up of 63 per cent of the group of companies, under study by NCAER, also included sales promotional costs.

The NCAER study while summing up noted, "To minimise the losses the units seem to curtail productions of formulations belonging to these categories." However, in the study report itself the authors could not prove (Ref. pages 163-164) that the profitability of certain groups of units correspondingly declined due to lower mark-up in categories I and II formulations.

We have dealt in some details with the NCAER report since the OPPI launched an intensive campaign on the basis of this report and demanded revision of DPCO 1979.

A general impression has also been created that the drug industry is not earning sufficient profits due to DPCO 1979. Lovraj Committee, which was set up in May 1978 to investigate the allegations of large profits by foreign companies, in its report of July 1979 had suggested that the effect of DPCO 1979 on the profitability of the drug industry should be assessed periodically. So far no attempt has been made by the Government to monitor periodically the drug units' profit in relation to DPCO 1979. In the absence of such an authentic study, no definite conclusion can be drawn on the actual effect of DPCO 1979 on the profitability of drug firms.

However, inferences can be drawn from the various reports since DPCO 1979. Economic Times on 30 July 1984 reports, "The financial performance of 33 pharmaceutical companies substantially improved during 1982-83. The net sales, income, gross profits and net profits of these companies increased during the year."

On 7 August, 1984 Financial Express reports, "The pre-tax profits of major wholly Indian private sector drug firms have risen substantially during the first three financial years of the current decade. The impressive results assume special significance in the light of repeated

allegations made by wholly Indian drug firms that foreign equity firms have been reaping profits. What is more, these results have been achieved under the much maligned 1978 drug policy."

Economic Times of 1 January 1986 reports, "Pharmaceutical companies in private corporate sector witnessed an allround improvement in their financial performance during 1984-85 enabled pharmaceutical companies to achieve better turnover, higher profits, impressive cash flow and an improvement in major profitability ratio during 1984-85 as compared with that in 1983-84."

The Financial performance of a few companies selected at random shows impressive profitability :

Company	Financial year ending	Pre-tax profit (Rs. in crores)
1. Hoechst	1984	2.23
2. Pfizer	1984	5.56
3. May & Baker	1984	4.01
4. Glaxo Labs.	1984	11.29
5. E. Merck	1985	1.85
6. Abbott	1985	0.62
7. Eskayef	1985	9.23

As mentioned above, the Tariff Commission and subsequently BICP made extensive studies on the costing of drugs. However, cost study of BICP on drugs has not yet been published by the Government, from which one could have come to definite conclusions on break-even mark-ups for drugs.

An impression has also been created that while raw materials and other input costs are going up, the prices of finished products are not allowed to be increased. Usual administrative delays, where administrative corrections are required, has nothing to do either with the Drug Policy or with the DPCO 1979. This cannot be the basis for upward revision of mark-ups. Besides, the prices of a substantial numbers of bulk drugs and formulations are being revised periodically, thereby resulting in price increase of drugs.

Self-Reliance

Efforts at self-reliance in a developing country are essentially geared for the national science and technology policies, and their implementation is directed towards meeting specific requirements of that country and also used as a weapon for struggle against the international industrial property system.

Better flow of technology by itself will not resolve the problem of technological dependency of the developing countries. Acquisition of

technology is no substitute for indigenous research and development (R & D) efforts.²³

Disease patterns of developing countries have rarely been taken into account by the large pharmaceutical houses. Contrary to this the R & D efforts by transnational corporations in developing countries has been oriented to the disease patterns in industrialised countries.²⁴

As discussed earlier the production and supply of drugs do not correspond with the disease pattern in this country. The multinational drug companies, on whose technological support we heavily relied in respect of pharmaceuticals, did not contribute much in research and technological development to meet the specific requirements of the country.

The study of National Institute of Science, Technology and Development Studies (NISTADS) and the Management Development Institute (MDI) revealed that the public sector in drug industry not only developed processes for production of a large number of essential and life-saving drugs but also tried to produce them from a more basic stage.

Contrary to this, the companies in Indian private sector and multinational sector preferred to produce these drugs from intermediate or penultimate stages. While the companies in Indian private sector tried to develop indigenous technology for production of drugs, wherever possible, the multinationals depended upon their parent companies for technology.²⁵

The Drug Policy, 1978 has a provision which states that foreign companies with more than Rs. 5 crores annual turnover should maintain R & D facilities within the country with a least 20 per cent of their net block and spend 4 per cent of annual sales turnover as recurring expenditure.

In a revealing statement in the Parliament the Government informed that information regarding R & D expenditure, both capital and recurring, incurred by the foreign drug companies, were not available with the Government.²⁶

In reply to a question in the Parliament the Minister for Chemicals admitted that these provisions of the Drug Policy could not be implemented as it required amendment of Industrial Development and Regulation Act.

In spite of all these shortcomings in indigenous R & D, it is to the credit of Indian scientists and technicians that all essential drugs as identified by UNIDO, are produced in India except Primaquine, as reported in the UNIDO meeting of 1980.

Yet we are relying on the multinationals for supply of technology for the production of essential drugs. It is a well known fact that the transfer of technology is closely linked to licensing agreements which include the concept of secret know-how, copyright etc. Secret know-how could be viewed as a type of exclusive property like a patent.

The demand for an International Code of Conduct on the Transfer of Technology, which was submitted by the Group of 77 (Pugwash Code), has

not been accepted. If accepted this would provide a legal instrument for supply of technologies on equitable terms and conditions.

Likewise, the trade mark and patent rights are big constraints on the growth of the pharmaceutical industry. UNIDO reports, "The strongest point which permits the domination of transnational pharmaceutical corporations is rooted in the patent and brand names systems."²⁷

In a resolution on the Action Programmes on Essential drugs adopted by World Health Assembly, member states were urged to enact legislation covering amongst other things the use of prescription drugs by generic names.²⁸

The fifth conference of the heads of states and governments of non-aligned countries held at Colombo in Sri Lanka, in August 1976 adopted a resolution for a list of priority pharmaceutical needs; establishment of a national buying agency to undertake purchase and supply of pharmaceuticals; recommending exclusion of pharmaceutical products from the grant of patent rights; elimination of brand names and adoption of generic names; etc. (Appendix-12)

Hathi Committee recommended abolition of brand names in a phased manner. The committee selected thirteen drugs, recommending their sale only in generic names. (Appendix-13) The Committee also suggested supply to government and municipal hospitals single ingredient drugs only in generic names and further recommended introduction of new drugs also in generic names. The Committee also suggested that the Indian Pharmacopoeia Committee should devise simple, short and suitable non-proprietary names of drugs which have long and difficult generic names.

The 1978 drug policy decided to abolish the brand names of the following single ingredient drugs :

Analgin	Ferrous Sulphate
Aspirin	Piperazine and its salts
Chlorpromazine	

The Ministry of Health and Family Welfare issued the necessary notification in January 1981 under the provisions of Drug and Cosmetics Rules. The Government also decided that no new single ingredient drug be marketed under a brand name. The amendments of the rules have come into effect from 1 August 1981.

Both these orders of the Government were opposed by the drug firms for obvious reasons. Hoechst, Cyanamid and Pfizer obtained stay orders against the Government's notification from the Delhi high Court.²⁹ The Central Government moved an appeal in the Supreme Court in 1982 against Delhi High Court's decision declaring that forcing the drug units to market new single ingredient drugs under generic names was illegal and ultra vires of the Constitution. The appeal of the Government is still pending before the Supreme Court.

In another judgement the Bombay High Court had ruled that Unichem should be granted requisite permission by Drug Controller (India) to market their new drug under brand name subject to final disposal of the brand name case by the Supreme Court.

It is unfortunate that the high-power Cabinet Committee on Economic Affairs has decided to do away with the existing stipulation in the industrial licences restricting the use of foreign brand names. FERA companies, the Committee decided, would be free to use the same brand name, as were being used by their parent companies overseas. They would be permitted use of foreign brand names for marketing life-saving drugs.³⁰ Such a decision of the Government defeats the very purpose and objective of Drug Policy decisions.

Smt. Indira Gandhi, while addressing the 156-nation World Health Assembly at Geneva on 6 May 1981, called for abolition of patents for medical discoveries. She said that her idea of a better world was one, "in which medical discoveries would be free of patents". But during her life time itself the Government of India started moving backward in respect of patent rights. An inter-ministerial committee of the Central Government had been formed to review the working of the Indian Patent Act of 1970. The Controller General of Patents, Designs and Trade Marks sent out letters to associations of drug manufacturers in March 1984, suggesting changes which virtually restored the provisions of the repealed patent Act of 1911.³¹ Under the Indian Patent Act, 1970 the patents for drugs are restricted to processes and not products. The term of drug patents is five years from the date of ceiling or seven years from the date of patents. The provisions of 1970 Act came into force in April 1972.

The monopolistic trend in the market through brand names, patent rights and other restrictive provisions in the production and supply of drugs has hindered the growth of a national pharmaceutical industry in spite of scientific and technological capabilities to meet the actual health needs of the people as far as drugs are concerned.

The TNCs have systematically built up an image. To maintain this image amongst the medical profession, the drug firms must project their product exclusiveness. Here comes the need for a brand name. Further, to keep their image of research and innovativeness, the drug firms are continuously coming with new product mixes leading to innumerable irrational drug combinations. As such the brand names and patent right have given rise to a number of problems which hinder the building up of the drug industry in India.

Another disturbing situation prevailing today, hindering the efforts towards self-reliance, is the import of large quantities of drugs every year; which should not be viewed as just a problem of balancing the import and export trade.

As against total bulk drug production of Rs. 325 crores, the country imported bulk drugs and intermediates worth Rs. 163.34 crores.³² This means, the imports to production ratio was about 1 : 2.

As stated earlier, the issue is not just balancing foreign trade, as the Government views it. A closer examination of the trend of imports reveals certain other areas, which should be of concern to the country's efforts towards self-reliance.

A large quantity of imports of penultimates from the world market affects production in the country. The import of L-Base for the manufacture of Chloramphenicol seriously affected its production in the country from more basic stage. Similarly, import of Tetra-urea for sometime affected production of tetracyclines in IDPL. Many penultimates are similarly being imported in the country which resulted in partial or total closure of factories in the country.

Some of the newer drugs, which have been imported in bulk replacing the drugs of same therapeutic groups have affected the indigenous production leading to closure of factories manufacturing these drugs. Imports of Rifampicin and Pyrizinamide worth Rs. 17.43 crores³³ during 1983-84 have seriously affected production of INH, PAS and Thiacetazone in the country.

Formulating A National Drug Policy

This is the background in which the Government propose to introduce a new Drug Policy.

The Hathi Committee Report of 1975 prepared the basis of a National Drug Policy in the country. Even though major recommendations of the Hathi Committee were ignored in the country's first Drug Policy of 1978, it attempted to put limited check and control on the multinational drug firms; gave encouragement to national private sector; the leading role of public sector in drug production was recognised as an objective; made a beginning with abolition of brand names of some drugs; attempted to make a graded essential drug list; attempted for a price differential on the basis of graded list of drugs; and recorded the intention of encouraging indigenous research and development.

The proposed drug policy of the Government intends doing away with many of these provisions, while the issue of brand names has been left to the decision of the Supreme Court.

In this situation, all sections of the people should come together to formulate a national drug policy which can fulfil the actual requirements of drugs in pursuance of a democratic health policy.

APPENDIX-1

Number (Estimated) of Persons Suffering from
Prevalent Diseases in 1980

	<i>No. of persons</i>
Filaria (Parasitic Stage)	18.00 million
T.B. (Acute Pulmonary)	10.00 million
Malaria	2.84 million
Leprosy	3.30 million
Enteric Fever*	0.30 million
Dysentery*	5.70 million
Gastro-enteritis*	0.80 million

* Assam, Bihar, West Bengal, J & K, Manipur and Nagaland were not included.

Source : 1. Health Statistics of India 1981, Ministry of Health and Family Welfare.

2. Rajya Sabha Proceedings — September, 1981.

APPENDIX-3

Actual Production of Some Essential Drugs

(Accounting Unit : Tonnes)

<i>Drugs</i>	<i>1980</i>	<i>1981</i>
	<i>(April to September)</i>	<i>(April to September)</i>
Chloramphenicol	46.41	36.16
PAS and its salts	215.16	122.22
INH	69.18	53.70
Iodochlor-Hydroxy-Quinoline	77.65	47.73
Piperazine Hexahydrate	6.30	4.20
Dapsone	10.28	10.17
D.E.C. Citrate	10.58	8.42

Source : Reply of Question in Lok Sabha, 15 December, 1981.

APPENDIX-2

Production of Some Essential Drugs (By DGTU Units only)
(Accounting Unit : Tonnes)

<i>Products</i>	<i>1976</i>		<i>1977</i>		<i>1978</i>	
	<i>Installed Capacity</i>	<i>Production</i>	<i>Installed Capacity</i>	<i>Production</i>	<i>Installed Capacity</i>	<i>Production</i>
Streptomycin	257	224	337	208.9	337	240.8
Chloramphenicol	128.8	93	129.8	90.6	129.8	82.5
Halogenated Quinoline	490.6	190	474.4	143.66	474.4	200.8
D.D.S. and its derivatives	23.3	18	25.8	16.3	25.8	15.9
I.N.H.	374.56	98	473.56	56.5	473.56	95.6
PAS and its salts	1170	695	1350	564.70	1350	552.21
Thiacetazone	152.6	14	142.56	22.94	142.56	12.47
Quinine and its salts	—	17	—	15.9	—	25.8
Diethyl C.C.	56	11	56	18.69	56	21.1
Piperazine and its salts	—	118	—	108.9	—	55.3

Source : DGTU Annual Report 1978-79

W.H.O's Criteria for the Selection of Essential Drugs

- (a) Adoption of a list of essential drugs is part of a national health policy. This implies that priority is given to achieving the widest possible coverage of the population with drugs of proven efficacy and safety, in order to meet the needs for prevention and treatment of the most prevalent diseases.
- (b) Only those drugs for which adequate scientific data are available from controlled studies should be selected.
- (c) Each selected pharmaceutical product must meet adequate standards of quality, including when necessary, bioavailability.
- (d) Concise, accurate and comprehensive drug information drawn from unbiased sources should accompany each list of essential drugs.
Criteria for the selection of essential drugs are intended to ensure that the process of selection will be unbiased and based on the best available scientific information, yet allow for a degree of variation to take into account local needs and requirements. The following guidelines are recommended :
 - (i) Each country should appoint a committee to establish a list of essential drugs. The Committee should include individuals competent in the fields of clinical medicine, pharmacology and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, assistance from WHO could be sought.
 - (ii) Drug selection should be based on the results of benefit and safety evaluations obtained in controlled clinical trials and/or epidemiological studies.
 - (iii) The international non-proprietary (generic) names for drugs or pharmaceutical substances should be used whenever available. A cross-index of non-proprietary names should initially be provided to the prescribers.
 - (iv) Regulations and facilities should be available to ensure that the quality of selected pharmaceutical products meet adequate quality control standards, including stability and, when necessary, bioavailability. Where national resources are not available for this type of control, the suppliers should provide documentation of the product's compliance with the requested specifications.
 - (v) Cost represents a major selection criterion. In cost comparisons between drugs, the cost of the total treatment, and not only the unit cost, must be considered. In addition, the cost of non-

- pharmaceutical therapeutic modalities should be taken into account.
- (vi) Local health authorities should decide the level of expertise required to prescribe single drugs or a group of drugs in a therapeutic category. Consideration should also be given to the competence of the personnel to make a correct diagnosis. In some instances, while individuals with advanced training are necessary to prescribe initial therapy, individuals with less training could be responsible for maintenance therapy.
- (vii) The influence of local diseases or conditions on pharmacokinetic and pharmacodynamic parameters should be considered in making the selections : e.g., malnutrition, liver disease.
- (viii) When several drugs are available for the same indication, select the drug, pharmaceutical product and dosage form that provide the highest benefit/risk ratio.
- (ix) When two or more drugs are therapeutically equivalent, preference should be given to :
 - (1) the drug which has been most thoroughly investigated;
 - (2) the drug with the most favourable pharmacokinetic properties, e.g. to improve compliance, to minimize risk in various pathophysiological states;
 - (3) drug for which local, reliable manufacturing facilities for pharmaceutical products exist;
 - (4) drugs, pharmaceutical products and dosage forms with favourable stability, or for which storage facilities exist.
- (x) Fixed-ratio combinations are only acceptable if the following criteria are met :
 - (1) clinical documentation justifies the concomitant use of more than one drug;
 - (2) the therapeutic effect is greater than the sum of the effect of each;
 - (3) the cost of the combination product is less than the sum of the individual products,
 - (4) compliance is improved;
 - (5) sufficient drug ratios are provided to allow dosage adjustment satisfactory for the majority of the population.
- (xi) The list should be reviewed at least once a year and whenever necessary. New drugs should be introduced only if they offer distinct advantages over drugs previously selected. If new information becomes available on drugs already in the list that clearly shows that they no longer have a favourable benefit/risk ratio, they should be deleted and replaced by a safer drug. It should be remembered that for the treatment of certain conditions, non-pharmacological forms of therapy or no therapy at all, may be preferable.

APPENDIX-5

**List Of 17 Essential Bulk Drugs Enlisted
In Tariff Commission Report, 1968**

1. Vitamin A
2. Vitamin B₁₂
3. Vitamin C
4. Sulphadiazine
5. (i) Penicillin Potassium G
(ii) Sodium Penicillin G
(iii) Procaine Penicillin
(iv) Potassium Penicillin V
6. Streptomycin
7. Chloramphenicol Powder
8. Tetracycline
9. Amodiaquine
10. Chloroquin Phosphate
11. Iodo-Chloro-hydroxyquinoline
12. Chloropropamide
13. Tolbutamide
14. Insulin
15. Isonicotonic Acid Hydrazide
16. (i) Sodium Salt of Para Amino Salicylic Acid
(ii) Para Amino Salicylic Acid
17. Prednisolone

Source : Background papers of National Convention on Economic Independence and Perspective of Drug Industry, New Delhi 21 December 1974, page XLIX.

APPENDIX-6

Essential Drug List Of Hathi Committee

Tablets and Capsules (Granules included)

1. Cap Chloramphenicol 250 mg.
2. Cap. Tetracycline Hydrochloride 250 mg.
3. Tab. Iodochlorhydroxy Quinoline 0.5 gm.
4. Tab. Nitrofurantoin
5. Tab. Chlorpheniramine

- ✓ 6. Tab. Ferrous Sulphate
7. Tab. Folic Acid
8. Tab. Digoxin
9. Tab. Aspirin
10. Tab. Phenobarbitone
11. Tab. Chlorpromazine
12. Tab. Prednisolone
13. Tab. Hexa Vitamin (N.F.I)
14. Tab. Vitamin B. Complex
15. Tab. Vitamin C
16. Tab. Sulphadimidine
- ✓ 17. Tab Metronidazole
18. Tab. Hydrochlorothiazide
19. Tab. Reserpine
20. Tab. Glyceryltrinitrate
21. Tab. Analgin
22. Tab. Antacid (B.N.F)
23. Tab. Piperazine (Syrup Piperazine)
24. Tab. Tetrachlorethylene
25. Tab. Tolbutamide
26. Tab. Thiacezone & Isoniazid (each tablet to contain Thiacezone 37.5 mg. BPC & Isoniazid 75 mg. IP)
27. PAS granules
- ✓ 28. Tab. I.N.H.
- ✓ 29. Tab. Dapsone (50 mg.)
- ✓ 30. Tab. Chloroquine Sulphate 0.2 gm. (or Tab. Chloroquine Phosphate 0.25 gm. IP)
- ✓ 31. Tab. Primaquine Diphosphate (2.5 mg. of Primaquine base)
- ✓ 32. Tab. Diethylcarbamazine Citrate (50 mg.)
33. Tab. Anti-asthmatic (containing ephedrine Hcl. 50 mg. Theophylline 65 mg. and Phenobarbitone 30 mg)
34. Tablets containing alkaloids of Ergot equivalent to 0.4 mg of total alkaloids ergotoxin.
35. Capsules of Vitamin A 6000 units and Calciferol 1000 Units.
36. Tab. Vitamin A
37. Tab. Vitamin D
38. Tab. Milk of Magnesia
39. Oral Contraceptive (approved by Family Planning Department)

Injections

1. Injection Penicillin
2. Inj. Streptomycin
3. Inj. Emetine Hydrochloride
4. Inj. Atropine
5. Inj. Adrenaline
6. Inj. Nor-Adrenaline
7. Inj. Dextrose Saline
8. Inj. Frusemide
9. Inj. Morphine Sulphate
10. Inj. Pethidine
11. Inj. Paraldehyde
12. Inj. Prednisolone
13. Inj. Anti-Tetanus Serum
14. Inj. Methyl Ergometrin
15. Inj. Chlorpheniramine Maleate
16. Inj. Fortified Benzyl Penicillin PP (Procaine Benzyl Penicillin 3,00,000 units. Benzyl Penicillin 1,00,000 units).
17. Inj. Aminophylline (0.5 gm/2ml)
18. Inj. Oxytocin (Oxytocin 5 i.u./ml)
19. Inj. Chlorpromazine
20. Antivenom Serum (Polyvalent)
21. Rehydration fluid (for treatment of cholera cases)
22. Glucose Ampoule (containing dextrose 25%)
23. Distilled Water (25cc ampoule)
24. Inj. Phenobarbitone Sodium (200mg/ml)
25. Inj. Mephenteramine
26. Diphtheria-Pertussis-Tetanus Vaccine
27. Inj. Tetanus Toxoid
28. Inj. Diphtheria Toxoid
29. Inj. Anti Diphtheria Serum
30. Oral Polio Vaccine
31. Inj. Insulin Plain (40 units per ml)
32. Inj. Sodium Pentathol
33. Inj. Succinyl Choline
34. Inj. Xylocaine

*Miscellaneous (Syrups, Ointments, Mixtures,
Eye-drops, Ear-drops, etc.)*

1. Sulphacetamide Eye Drops
2. Homatropine Eye Drops

3. Eserine Sulfate Eye Drops
- ✓ 4. Benzyl Benzoate Emulsion
5. Acid Carbohc
- ✓ 6. Lysol
- ✓ 7. Tr. Iodine
8. Syrup Piperazine
9. Ext. Belladonna (Combination of Phenobarb & Belladonna)
10. Chloramphenicol Suspension (125 mg/ml)
11. Syrup Paracetamol (125 mg in 5 ml)
12. Tetracycline Hydrochloride Ointment 1% in sterile ointment base
13. Gripe Mixture for infants (5 ml contains Dill oil BPC 0.005 ml; sodium bicarbonate I.P.O. 0.005 gm dehydrated alcohol I.P. 0.0248 ml (Syrup & Preservative).
14. Syrup Noscaphine
15. Whitefields Ointment (Benzoic acid 6 g; salicylic acid 32g; alcohol 70% upto 100g)
16. Nitrofurazone Ointment (0.2% in non-greasy ointment base)
17. Petroleum Jelly
- ✓ 18. Potassium Permanganate 5g packets
19. Diethyl Ether (Anaesthetic)
20. Cetrimide Lotion
- ✓ 21. Iodine Solution (Claudium Solution) for sterilizing raw catgut, loops and loop introducers (Iodine 1 g, Pot. Iodide 1.5 g, Distilled Water to produce 100 ml)
- ✓ 22. Plaster of Paris Bandages
- ✓ 23. Adhesive Plaster
24. Ethyl Chloride (100 ml spray)
25. Boric Acid-Alcohol-Glycerol drops (Boric Acid 1.5% Glycerol 3.3% in alcohol 95%, 10 ml)
- ✓ 26. Bleaching Powder
- ✓ 27. Phenyl
28. Epsom Salt
29. Krushen's Salt (Each gram contains Sod. Sulphate Exsic 20 mg., Sod. chloride 10 mg., Pot. chloride 10 mg, Potassium Sulphate 55 mg., Citric Acid 45 mg., Magnesium Sulphate Exsic).

- ✓ 30. Ointment containing : Resublimed Iodine 4%, Methyl Salicylate 5%
- ✓ 31. Ointment containing : Oil Eucalyptus 8%, Oil Clove 1%, Camphor 5%, Menthol 3%, Thymol 2%, Methyl Salicylate 5%.

APPENDIX-7

Drug Policy, 1978

List Of Highly Essential & Life-Saving Drugs

Category I Formulations

1. Aspirin Tablets
2. Digoxin Tablets
3. DDS Tablets
4. DPT Vaccines
5. Hydrochlorothiazide Tablets
6. Insulin Injection (all sorts)
7. Iodo-chloro-hydroxy-quinoline Tablets and Di-iodo-hydroxy-quinoline Tablets
8. INH Tablets
9. INH plus Thiacetazone Tablets
10. Morphine Sulphate Injection
11. PAS and its Salts, Granules and Tablets
12. Penicillin Injection including Procaine Penicillin, Penicillin G and Benzathine Penicillin
13. Pethidine Injection
14. Phenoxymethyl Penicillin Tablets
15. Primaquin Phosphate Tablets*
16. Streptomycin Injection plus combination with Penicillin
17. Tolbutamide Tablets*

Category II Formulations

1. Analgin Tablets
2. Amodiaquin Tablets
3. Calcium Benzoyl PAS Tablets
4. Chloramphenicol oral preparations including Chloramphenicol Palmitate, Suspension and Syrup and Chloramphenicol Sodium Succinate Injectable

5. Chloramphenicol in combination with Streptomycin
6. Chloroquin Salts
7. Diethyl Carbamazine Citrate Tablets
8. Diphtheria Tetanus Toxoid Injection
9. Frusemide Tablets, Injection
10. Glyceryl Trinitrate Tablets
11. Phenobarbitone Tablets
12. Phthalyl Sulphathiazole Tablets
13. Piperazine and its Salts — Tablets, Syrup
14. Prednisolone Tablets and Injection
15. Primaquin Tablets**
16. Quinine Salts, Tablets and Injection
17. Sulphadimidine Tablets
18. Tetanus Toxoid Injection
19. Tetracyclines Capsules, Tablets, Syrup, Injection, Eye Ointment (including Oxy-Demethyl-Chloro and Pyrolidine Methyl Tetracyclines)
20. Tolbutamide Tablets**

APPENDIX-8

National Priority List Of Bulk Drugs As Proposed
In The Steering Committee Report

Anaesthetics

1. Ether Anaesthetic
2. Halothane
3. Thiopental
4. Lidocaine/Procaine
5. Nitrous Oxide

Analgesics, Antipyretics Etc

6. Aspirin
7. Ibuprofen*
8. Paracetamol*

Anti-Allergics

9. Chlorpheniramine
10. Epinephrine

Anti-Infectives

(a) Anthelmintic

11. Mebendazole*
12. Piperazine
13. Bephenium Hydroxy Naphthoate

(b) *Antiamoebic*

14. Chloroquine
15. Metronidazole

(c) *Antimicrobial*

16. Ampicillin
17. Benzathine Benzyl Pencillin
18. Benzyl Pencillin
19. Procaine Benzyl Penicillin
20. Chloramphenicol
21. Sulphadimidine
22. Sulphamethoxazole
23. Trimethoprim
24. Tetracyclines
25. Oxytetracycline
26. Erythromycin

Anti-Leprosy

27. Clofazimine
28. Dapsone
29. Rifampicin

Anti-TB

30. Ethambutol
31. Isoniazid
32. Pyrazinamide
33. Streptomycin
34. Thiacetazone

Anti-Filarial

35. Diethylcarbamazine

Anti-Fungal

36. Griseofulvin

Anti-Malarial

37. Primaquine
38. Amodiaquine

Immuno-Suppressive

39. Busulphan
40. Chlorambucil
41. Cyclophosphamide
42. Flurouracil

Antianaemic

43. Ferrous Salts*
44. Folic Acid
45. Hydroxycobalamine/Cyanocobalamine

Plasma Substitute

46. Dextran

Cardio Vascular

47. Glyceryl trinitrate
48. Isosorbide dinitrate
49. Propanolol
50. Verapamil
51. Hydrallazine
52. Hydrochlorothiazide
53. Methyldopa
54. Digoxin

Dermatological

55. Neomycin
56. Bacitracin
57. Betamethasone
58. Benzyl Benzoate

Ophthalmic Drugs

59. Sulphacetamide
60. Pilocarpine
61. Homatropine

Disinfectants

62. Chlorohexidine
61. Certrimide
64. Dettol (Xylenol)

Diuretics

65. Frusemide

Gastro-Intestinal

66. Promethazine
67. Oral Rehydration Salts (deleted in the meeting of Steering Committee)

Hormones

68. Dexamethasone
69. Prednisolone

Oral Contraceptives

- 70. Ethinyl Oestradiol
- 71. Levenorgestrol
- 72. Nerethisterone

Anti-Diabetics

- 73. Insulins
- 74. Glybenclamide
- 75. Chloropropamide
- 76. Tolbutamide

Muscle Relaxants

- 77. Neostigmine
- 78. Suxamethonium

Oxytocins

- 79. Ergometrine/methyl ergometrine
- 80. Oxytocin

Psychotherapy Drugs

- 81. Amitriptyline/Imipramine
- 82. Chlorpromazine (substituted)
- 83. Trifluoperazine

Respiratory

- 84. Aminophyllin/theophyllin
- 85. Hydroxy Ethyl Theophyllin
- 86. Salbutamol*
- 87. Ephedrine

Vitamins

- 88. Vitamin A
- 89. Vitamin D
- 90. Vitamin C
- 91. Nicotinamide
- 92. Pyridoxine
- 93. Pantothenates
- 94. Riboflavin
- 95. Thiamine

* Decided as requiring special attention for encouraging production.

APPENDIX-9

Supply of INH And PAS

PFIZER LIMITED

Inter-Office Memorandum

Date : May 26, 1981

CONFIDENTIAL

To : Regional Managers

From : A. G. Kamath — Bombay

Circular No. 10.81

Subject : HOSPITAL BOOKING CAMPAIGN — 2nd HALF 1981

With reference to the discussions we had this morning at RMs' Conference, you are hereby authorised to institute Hospital Booking Campaign for the following items :

Item	Unit	Special Price
Terramycin Caps,	100s	42.60
Terramycin Skin Oint.	5g	1.48
Terramycin Skin Oint.	15g	2.20
Fenocin 65 mg Tabs.	100s	19.31
Fenocin Forte Tabs.	100s	30.00
Combiotic 0.5 g (5 Dose)		
Streptopen 0.5 g (5 Dose)	Vial	5.08
Deltacortril Tabs	1000s	145.00

For FENOCIN FORTE Tabs, if you need lower than Rs. 30.00, please contact us with the name of the customer, competitive price, quantity involved, delivery schedule, etc.

These special prices are valid upto November 30, 1981

Betacortril Parenteral :

Some of the Depots are holding large quantities with less than six months shelf life. Efforts should be made to dispose of the entire stocks at a price exceeding Rs. 4.80 per vial, to minimise the loss on write-offs.

NSA Injectables and Anti-TB Drugs :

* The availability of Narrow Spectrum Injectables (with the exception of COMBIOTIC 0.5 g Dose/STREPTOPEN 0.5g 5 Dose) and Anti-TB dosage forms will be very uncertain.

Therefore, HOSPITAL PRICES shown in our SCHEDULE OF PRICES dated July 1, 1980 are hereby withdrawn for the following items :

Diapen 6 lacs
PPF-20

Isonex 100 mg 1000 Tabs
Isonex 100 mg 5000 Tabs

Pronapen 5 Dose	Isonex Forte 1000 Tabs
Pronapen 10 Dose	Isozone 1000 Tabs
Diapen-F 12 Lacs	Isozone Forte 1000 Tabs
PAS 100 g	
Sodium PAS 1000 g	

You should contact H.O. seeking guidance on the availability and prices for the above items, before making any commitment.

Please acknowledge receipt of this circular by returning the following slip duly signed by you.

** Italics incorporated*

Sd/-
A. G. Kamath

APPENDIX-10

Notification of Banned Drugs

List of Banned Drugs

Ministry of Health & Family Welfare, New Delhi, the 23rd July, 1983

G.S.R. 578 (E) — Whereas the Central Government is satisfied that the use of the Drugs specified in the table below is likely to involve risk to human beings or the said drugs do not have the Therapeutic value claimed or purported to be claimed for them or contain ingredients and in such quantity for which there is no therapeutic justification and it is necessary and expedient in the public interest so to do :

Now, therefore, in exercise of powers conferred by Section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture and sale of the said drugs namely :

TABLE

1. Amidopyrine
2. Fixed dose combination of Vitamins with anti-inflammatory agents and Tranquillisers
3. Fixed dose combination of Atropine in Analgesics and Antipyretics
4. Fixed dose combination of Strychnine and Caffeine in tonics
5. Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins
6. Fixed dose combination of Iron with Strychnine, Arsenic and Yohimbine
7. Fixed dose combination of Sodium Bromide Chloral Hydrate with other drugs

8. Phenacetin
9. Fixed dose combination of Anti-histaminic with anti-diarrhoeals
10. Fixed dose combinations of Penicillin with Sulphonamides
11. Fixed dose combinations of Vitamins with analgesics
12. Fixed dose combinations of Tetracycline with Vitamin C
13. Fixed dose combinations of Hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery and for external use only.
14. Fixed dose combinations of Steroids for internal use except combinations of Steroids with other drugs for the treatment of Asthma
15. Fixed dose combinations of Steroids Chloramphenicol for internal use except combinations of Chloramphenicol and Streptomycin
16. Fixed dose combination of Ergot
17. Fixed dose combination of Vitamins with anti-T.B. drugs except combination of Isoniazide with Pyridoxine Hydrochloride (Vitamin B6)
18. Penicillin Skin/Eye Ointment
19. Tetracycline Liquid oral preparations
20. Nialamide
21. Practolol
22. Methapyrilene, its salts
(No. X. 11014/1/83-DMS & PFA)

S. V. Subramaniyan,
Jt. Secretary

ADDENDUM

23. Methaqualone
24. Oxytetracycline liquid oral preparations
25. Demeclocycline liquid oral preparations

**Original Equity of Multinational Drug Firms* and Remittances
Abroad by Drug Companies with More Than 26% Foreign
Equity During Fifth Five Year Plan****
(Rupees in lakhs)

Name of Company	Original Equity	Remittances abroad during				
		1974-75	1975-76	1976-77	1977-78	1978-79
Abbott	1.00	—	—	—	—	—
ACCI	35.34	25.90	8.20	54.30	17.55	44.60
Anglo-French	0.10	—	0.01	0.90	2.22	2
✓ Bayer	4.00	—	0.01	23.28	35.79	46.54
Boehringer Knoll	15.00	—	—	6.57	4.72	3.45
Boots	10.00	0.72	8.74	6.75	10.53	13.80
Burroughs Wellcome	5.00	—	3.91	33.20	13.83	13
C.E. Fulford	4.00	—	—	—	—	—
Ciba-Geigy	3.00	45.50	11.53	34.17	36.12	84.19 ✓
Curewell	—	—	—	—	2.02	—
Cyanamid	1.50	10.03	1.35	77.15	55.92	47.87
Duphar Interfran	8.00	NA	NA	2.54	2.29	1.50
E. Merck	20.00	—	—	3.17	3.53	3.07
Geoffrey Manners	0.01	—	9.49	20.32	22.99	22.68
German Remedies	—	NA	NA	3.16	4.26	4.58
Glaxo	—	—	62.84	86.44	131.33	120.82
Griffon	2.00	—	—	—	—	—
Hoechst	20.00	—	9.48	20.36	20.43	20.43
Indian Schering	0.835	—	—	—	—	—
Johnson & Johnson	20.00	—	4.21	13.96	18.40	11.54
Merck Sharp & Dohme	180.00	9.63	0.02	12.26	22.35	8.91
Nicholas	—	—	—	—	11.73	6.92
Organon	97.55	4.30	4.30	6.57	6.03	6
Parke Davis	87.50	—	—	49.66	42.45	55.12
✓ Pfizer	2.00	18.71	15.60	94.86	169.62	45.36
Rallis	—	NA	NA	12.22	13.62	1.16
Reckitt & Colman	30.00	NA	NA	16.41	16.41	9.35
Richardson Hindustan	0.02	8.99	—	14.14	14.42	14.85
Roche	10.00	16.52	8.59	30.74	24.15	20.02
Roussel	196	—	—	—	—	—
Sandoz	10.00	—	25.86	11.46	—	11.81
Searle	16.00	—	10.10	2.50	4.80	4.05
S. Geigy	7.20	—	—	—	—	—
Synbiotics	—	—	1.34	—	1.35	2.25
Uni-Sankyo	—	—	—	—	—	0.19
Wander	—	—	—	0.47	0.07	0.45
Warner Hindustan	70.00	7.52	9.59	19.92	28.02	19.64
Whiffens	—	0.31	—	0.20	0.38	0.94
Wyeth	33.30	8.16	4.45	11.13	17.29	10.99

Sources : * Hathi Committee Report, April, 1975/Page : 108-109

** Reply to Question in Lok Sabha, 8 September, 1981

**RESOLUTION ON CO-OPERATION AMONG DEVELOPING
COUNTRIES IN THE PRODUCTION, PROCUREMENT &
DISTRIBUTION OF PHARMACEUTICALS, ADOPTED AT
THE FIFTH CONFERENCE OF HEADS OF STATE OR
GOVERNMENT OF NON-ALIGNED COUNTRIES,
COLOMBO, SRILANKA, AUGUST 1976.**

The Conference,

Recalling the Non-Aligned Action Programme for Economic Co-operation among developing countries adopted at the Conference of Foreign Ministers of Non-Aligned Countries in Georgetown in August 1972, and approved at the Fourth Summit held in Algiers in September 1973,

Recalling also the Economic Declaration of that Summit calling for the further strengthening of economic co-operation among developing countries.,

Noting the inclusion of the production and distribution of medicine and medical substances in the Lima Programme for Mutual Assistance and Solidarity as an additional area of co-operation among developing countries,

Bearing in mind the possibilities for joint action by developing countries, identified in the study commissioned by UNCTAD on major issues in the transfer of technology to the developing countries in the pharmaceutical industry,

1. Endorses the recommendations of the Group of Experts on Pharmaceuticals which met in Georgetown in July 1976 and which proposes among other things :

(a) The preparation of a list of priority pharmaceutical needs of each developing country and the formulation of a basic model list of such needs as a general guidelines for action by the developing countries;

(b) The establishment of a national buying agency to undertake the purchase and supply of pharmaceuticals;

(c) That, in the context of the revision of the industrial property systems, consideration be given to excluding pharmaceutical products from the grant of patent rights or alternatively the curtailment of the duration of patents for pharmaceuticals;

(d) The elimination, wherever possible, of brand names and the adoption of the generic names for pharmaceuticals; and provision of information only from official sources;

(e) The establishment by each developing country of its own pharmaceutical industry as appropriate, beginning with formulation and packaging and building up to more complex production activities;

(f) The creation of Regional Co-operative Pharmaceutical Production and Technology Centres (COPPTECs), as proposed by UNCTAD and UNIDO, in order to draw up drug lists, to co-ordinate research and development, facilitate the transfer of technology, collect and disseminate information on pharmaceutical uses and prices and on the technological capabilities among member countries and also to co-ordinate the production and exchange of drugs between different member countries as well as between different regional centres;

2. *Invites* the relevant international organizations such as UNCTAD, UNIDO, WHO and UNDP to assist in the achievement of the objectives outlined in operative paragraph 1 above with particular regard to the establishment of appropriate National Pharmaceutical Centres in developing countries and Regional Co-operative Pharmaceutical Production and Technology Centres (COPPTECs) among them;

3. *Decides* further that the Co-ordinator of the Trade, Transport and Industry sector of the Non-Aligned Action Programme for Economic Co-operation among developing countries should take the necessary follow-up action to ensure early implementation of the provisions of this resolution.

Source: Guidelines on Technology Issues in Pharmaceutical Sector in the Developing Countries, UNCTAD/TT/49, United Nations, New York, 1982.

APPENDIX-13

Hathi Committee List of Essential Drugs for Sale Only in Generic Names

- | | |
|---------------------|-------------------------------|
| 1. Chloramphenicol | 7. Tolbutamide |
| 2. Tetracycline | 8. Analgin |
| 3. Ferrous Sulphate | 9. Piperazine |
| 4. Aspirin | 10. Crystalline Pencillin G |
| 5. Chlorpromazine | 11. Streptomycin |
| 6. Reserpine | 12. INH Tablets |
| | 13. Tablets INH-Thiacetazone. |

(All dosage forms of above drugs be marketed under generic names)

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Health, Diseases and Drugs

(Dr.) Naresh Banerjee *

Introduction

Man evolved "Health Care" to take care of the health of the people in cases of illness, injury and child birth. Procedures adopted and progress made in this sphere have undergone great changes. This has been brought about by human labour and intelligence, in keeping with Man's constant endeavour and struggle for existence for a better way of life and better type of health care by fighting not only against nature but also against exploitation by a section of human society.

In the process of social transition, "Health Care" has also undergone changes from magic, witch craft, tribal healers, religious practices, traditional remedial measures to a discipline of science, from individual art to a discipline of social science, from individual care to total social care, with priority for the under-served and the vulnerable sections of the population.

India has a glorious heritage of Ayurvedic Medicine since 3000 years B.C. (Rishi Indra, Shankaracharya, Artreya, Dhanwantari, Charaka, Sushruta, Jiboka, etc.) right upto 1500 AD. Subsequently due to repeated foreign invasions and foreign domination, with mixing up of various socio-economic, cultural and political set ups, its further progress was adversely affected, and it suffered from stagnation and decay. Since the 16th Century the Western system of medicines started penetrating and gradually dominated the Health Care System by the 19th Century to suit its own colonial purposes, neglecting the health care needs of the common people of our country.

After national independence in 1947, opportunities came to restructure our health care system to make it people oriented, promotive and preventive oriented and need based, befitting the socio-economic system and morbidity pattern of our country. But till today, 39 years after independence, after completion of six Five Year plans, after setting up several high power committees and commissions, no people oriented National Economic Policy,

National Agricultural Policy, National Health Policy and National Drug Policy etc. could be evolved, in keeping with the needs and priorities of our country.

As a result, in spite of some development in agricultural and industrial production, in spite of increase in the number of schools and colleges, in spite of increase in the number of medical teaching institutions, from 29 to 110, in spite of increase in number of doctors and paramedicals, in spite of increase in number of health care delivery units and hospital beds, in spite of increase in number of drug manufacturing units from 360 to 8,000 and increase in drug production from worth Rs. 10 crore to Rs. 1,930 crore, we find 60% of the people are below or bordering the poverty lines, 25% are suffering from starvation, 64% are illiterate, 70% of the people do not enjoy treatment facilities with modern drugs. Only 18% of the deliveries are attended to by trained people, infant mortality rate is still high at 120 per thousand, maternal mortality rate is 415 per one lakh live births. Of the 23 million children born in India every year only 3 million are healthy, about 3 million children die within the first year of their life, one out of seven die before the age of five, six out of ten suffer from malnutrition, and nine million limp into adulthood mentally and physically retarded mainly due to hunger. 75% of all the diseases in India are due to malnutrition, contaminated water and non immunisation.¹

Without taking into account such dismal socio-economic and health background and without taking into account the limiting factors, our deliberations on "Health, Disease and Drugs" as a part of "National Drug Policy" or "National Health Policy" or "Health for all by 2000 AD" cannot achieve the desired success. "Drugs" cannot satisfy hunger, cannot quench thirst, cannot substitute education or health education, nor can these provide sanitation, housing and viable employment.

"Health" is a Socio Economic and Political Issue

Present day concept of Health

"That Health which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of highest possible level of health is a world-wide social goal whose realisation requires the action of many other social and economic sectors in addition to the health sector".²

Health is Wealth

The health of the people is the basic input for national progress, economic, cultural and social development through productive mandays. "Illness, and injury are the major factors for mandays loss in India in comparison to strikes, closures and lockouts".³

* Dr. Naresh Banerjee is a Member of Therapeutic and Appliances Standing Committee of Indian Medical Association and Member of Health Advisory Committee, Government of West Bengal. He is also a past president of the Bengal Chapter of Indian Medical Association.

Health cannot be achieved by the health sector alone

To achieve health we need balanced food in adequate quantities, for which we need radical land reforms. For employment and adequate supply of essential commodities, we need better industrial relations. For health education, we need eradication of illiteracy which cannot be achieved by merely "setting up of education centres of excellence, one in each district with training facilities in computer technology".⁴ All dimensions of socio-economic conditions viz., food, water supply, education, housing, sanitation, employment etc. are vitally integrated to play a dominant role in maintaining health. This needs a determined political will on the part of the ruling political power at the Centre to shake off its colonial legacies and feudal backlog, to stop collaborating with the imperialist countries and pursuing the capitalist path of development. To safeguard the health of our people, radical social changes are essential with the active involvement of all the democratic organisations of the masses.

Common diseases of our Country and therapeutic measures required to treat them

Diseases due to deficiency in Food and Nutrition

Want of adequate food and nutrition makes an individual more prone to various diseases by lowering his immune status i.e., by lowering his power of resistance against diseases.

Gross Protein-Carbohydrate deficiency

Leads to conditions like Pellagra, Kwashiorkor and Marasmus. 20 per cent of children in rural areas and 10 per cent of children in urban slums suffer from these disorders.

These conditions can be prevented if adequate nutrition is provided and the children are immunised against communicable diseases.

Treatment for those affected is through supplementary foods, to increase intake of carbohydrates and proteins.

Vitamin A deficiency

Leads to conditions like Xerophthalmia, Keratomalacia and Night Blindness.

Children are most affected. About 40,000 children go blind and another 50,000 suffer from impaired vision every year due to Vit. A deficiency.

These conditions can be prevented by adequate supply of Vit. A in daily diet. Carrots, yellow vegetables, milk, eggs etc. are good sources of Vitamin A. Treatment is by Vitamin A. therapy.

Iron deficiency anaemia

This affects 50 per cent of children and 65 per cent of women — particularly those in the child bearing age group.

An overwhelming majority of cases can be prevented by adequate dietary intake. Foods rich in Iron include peas, beans, lentils, jaggery, plantains, liver, eggs and red-meat.

Drugs required for treatment are Iron Supplements viz., Ferrous Sulphate or Fumarate (as tablets, drops or injections), Folic acid and Hydroxycobalamine. Costly alcohol based tonics with a number of useless components have no place in therapy.

Thyroid gland disorder due to Iodine deficiency (Goitre)

10 to 15 per cent of people in the Himalayan and sub-Himalayan regions and 3-4 per cent in other parts of the country suffer from Goitre.

Goitre can be prevented by regular intake of iodised salt. Fresh vegetables and milk are also sources of Iodine.

Levothyroxine (Eltroxin) is the drug of choice for therapeutic purposes.

Deficiency of Vitamin B-Complex and Vitamin C

Disorders caused include Beri-Beri, Scurvy, Pellagra, Epidemic Dropsy, Polyneuritis, Glossitis, Dermatitis, Sores, Ulcers etc.

All these can be prevented if a balanced diet is taken. Pulses, green vegetables, unpolished rice, eggs, liver etc. are good sources of 'B' Vitamins. Citrus fruits like lemon and oranges, spinach, guava etc., are good sources of Vitamin C.

Therapy of deficiency conditions consists of supplementation by Vit. C or whichever 'B' vitamin is required. Here again high priced 'tonics' containing small amounts of almost everything have no place in therapy. Attempt should always be made if possible, to ascertain the existence of the particular kind of Vitamin deficiency before starting therapy.

Tetanus, Whooping Cough, Diphtheria, Polio, T.B, Measles, Mumps etc.

These diseases are being treated as a separate category as they can be almost totally prevented if children are properly immunised against them at the proper time. Yet today, these diseases are major causes of mortality and morbidity in our country.

The Expanded Programme of Immunisation (EPI) covered only 25 per cent of children till the end of the Sixth Five Year Plan. Further, only about 20 per cent of pregnant women and 30 per cent of people who sustain external injuries (the two high risk groups) could be protected from tetanus with Tetanus Toxoid injection till the end of the Sixth Plan Period.

Vector borne diseases

These include Malaria, Encephalitis, Filariasis, Leishmaniasis, (Kalazar), Dengue, etc. One-third of the total population of India is exposed to these diseases regularly, of which Malaria is most prevalent. Proper measures for environmental sanitation to destroy the breeding places of vectors, can bring down the incidence of these diseases drastically.

Principal drugs required to treat these conditions are Chloroquine, Amodiaquine, Quinine Sulphate and Primaquin for Malaria; Diethyl Carbamazone for Filariasis; and Pentamidine and Sodium Stibogluconate for Kalazar. Encephalitis and Dengue are viral disorders for which there is no specific anti-infective therapy — treatment consists of supportive measures.

Infective disorders of the Gastro-intestinal tract and liver

These include Gastroenteritis, Cholera, Infective hepatitis, Bacillary dysentery, Enteric Fever and Amoebic dysentery. These diseases are usually water or food borne. Infants and children are the worst sufferers. A majority of cases can be prevented by providing protected food, potable water and environmental sanitation.

Therapeutic agents required to treat these conditions are oral rehydration salts, glucose-saline I/V preparations, Furazolidine, Diloxanide Furoate, Metronidazole, Tinidazole, Salazosulpha-pyridine and Co-trimoxazole. Enteric Fever can be treated with Chloramphenicol and Cholera with Tetracycline.

Tuberculosis

It is one of the commonest endemic diseases in India. More than one crore people are afflicted by it with about 40 per cent sputum positive cases. 550,000 people die each year of T.B.

Majority of the cases can be prevented with BCG vaccination of children and hygienic conditions of living. Drugs required for treatment are Streptomycin, Ethambutol, Isoniazid (INH), Thiacetazone and Rifampicin.

Leprosy

About half a million people are afflicted with Leprosy in India of which 20 per cent are infective. Drugs required for treatment are Rifampicin, Clofazimine and Dapsone.

Worm infestations

70 per cent of children below the age of twelve and 20 per cent of adults suffer from various types of intestinal worm infestations. Drugs required for treatment are Mebendazole, Thiabendazole, Piperazine, Pyrantel and Bephenium hydroxynaphthoate.

Acute infections

These include Pneumonia, Enteric Fever, Otitis, Panophthalmitis, Cellulitis, Appendicitis, Septicaemia, Tonsillitis, Endometritis etc. Anti infective drugs required to combat these include Ampicillin, Amoxycillin, Penicillins, Chloramphenicol, Cloxacillin, Erythromycin, Gentamycin, Sulphadimidine, Salazosulphapyridine, Co-Trimoxazole, Doxycycline and Cephalosporin.

Cardiovascular diseases

These include Hypertension, Ischaemic Heart Disease, Cardiac arrhythmias, Rheumatic Heart Disease etc. There has been an increase in the incidence of these diseases among people from a higher socio-economic background due to sedentary habits, smoking and increased intake of food containing saturated fats. Further, Rheumatic Heart Diseases are prevalent among the poorer sections.

Drugs required for these conditions include : Antianginal drugs — Glyceryl trinitrate, Isosorbide dinitrate and Propanolol; Anti arrhythmic — Lidocaine, Propanolol, Quinidine and Procainamide; Antihypertensive — Hydralazine, Hydrochlorothiazide, Propanolol, Sodium Nitroprusside, Verapamil and Reserpine; Cardiac Glycosides — Digoxin, Digitoxin.

Other Gastro-intestinal diseases

Include disorders like Hyperacidity, Peptic Ulcer etc. These are common disorders and can be largely controlled by diet control.

Drugs required include Antacids like Aluminium Hydroxide and Magnesium Hydroxide; Antiemetics like Promethazine and Metoclopramide; Belladonna Alkaloids and Cimetidine.

Diabetes

Approximately 20 per cent of the population above the age of forty are suffering from Diabetes. Drugs required include Insulin (plain and zinc suspension), Tolbutamide, Glibenclamide and Chlorpropamide.

Obstructive airway diseases

Diseases in this category include Pulmonary Emphysema, Bronchial Asthma etc. Drugs required for therapy are Aminophylline, Sulbutamol, Adrenaline, Ephedrine. Prednisolone and Cromoglycic Acid (as inhaler).

Allergic reactions

Drugs required include Adrenaline, Cortisone and Chlorpheniramine Maleate.

Fever, pain and inflammation

Drugs required in these conditions are Aspirin, Paracetamol, Ibuprofen, Indomethacin and Pethidine.

Dermatological conditions

These include Fungal and Bacterial skin infections, Scabies and Allergic Dermatitis. Drugs required include Benzyl benzoate, Neomycin + Bacitracin, Betamethasone, Benzoic Acid, Salicylic Acid and Nystatin.

Antidotes

Commonly required antidotes are activated charcoal, Atropine, Deferoxamine, Sodium Thiosulphate, Sodium Nitrite, Sodium Calcium Edetate and Polyvalent Anti Snake Venom.

Anaesthetics

Anaesthetic agents required are Ether, Halothane, Nitrous Oxide, Thiopental, Bupivacaine and Lidocaine.

Vaccines

Vaccines required for prevalent diseases include BCG, Diphtheria-Pertussis-Tetanus (DPT) vaccine, Measles vaccine, Poliomyelitis vaccine, Meningococcal vaccine and Rabies vaccine.

Miscellaneous

Some categories of diseases and drugs have not been discussed in detail here. These include Anti-cancer drugs, Diuretics, Oral Contraceptives, Disinfectants, Ophthalmic Drugs, Hormones and Psychotropic drugs.

Condition prevailing in the sphere of drugs

In 1984 only 5 to 6 per cent of the people could afford or could procure modern drugs needed for their health care, another 25 per cent had access to modern drugs marginally or casually. Above 70 per cent of the people living in rural areas and urban slums, who are the principal victims of endemic and epidemic diseases have got no or only marginal access to treatment with modern drugs.

In the absence of a people oriented national Socio-economic policy, Health Policy and Drug Policy, the health care delivery system has been commercialized. This is more so in the case of the Drug Industry, in which profit priority supersedes health priority. "It is highly relevant for the developing world that "Drug Policy" should take into account not just technological and scientific aspects of drugs but economic and social aspects also. In India the Drug Policies are directly linked up with industrial and trade development, and are highly influenced by those sectors, rather than by health considerations, where profit priority supersedes health priority".⁵

The Government of India is committed to implement 'Health for All by 2000 AD'. Drugs being an essential component required to ensure primary health care for all, they must be made accessible to the whole population. This implies that in just 15 years from now, we shall have to extend the drug coverage from 25 per cent of the population, as at present, to 100 per cent.

There are over 50,000 drugs and chemicals in our formularies and pharmacopeas, out of which hardly 2000 drugs and chemicals are of some use for all types of health care including sophisticated care. W.H.O. has identified about 260 drugs (ranging from immunising vaccines to distilled water) as essential and life saving drugs with the remark "that each country should prepare the list, fixing priorities considering their health

need".⁶ Paying due consideration to the socio-economic condition of our country, the Hathi Committee (1976) had identified 117 drugs, and the working group of the National Drugs and Pharmaceutical Development Council has suggested in 1984, 96 drugs. With these, 90 per cent of the diseases commonly prevalent in our country could be treated, instead of spending huge sums on marginal remedies and sophisticated health care to serve the interest of hardly 10 per cent of our people. This list of essential drugs needs updating at regular intervals with minor regional variations to meet the regional morbidity patterns.

In the sphere of drug production, utter chaos and gross negligence of the peoples' health care prevails in spite of the recommendations of the Bhore Committee, Sokhey Committee, Mudaliar Committee, Naskar Committee and lastly, the Hathi Committee (1976). Of these Committees, the Hathi Committee laid the basic foundations of a National Drug Policy in all its aspects and exposed the massive exploitation of the people of our country by the Multinational Corporations and their Indian collaborators under the garb of health care remedies. "These companies apply price rigging, quality rigging, and ignoring the research need of the country to meet the demands of the most common diseases they rig quantum of production quota to switch on to profit oriented marginal remedies at the cost of essential drug production",⁷ and "utilise under-developed or developing countries as dumping ground for substandard and discarded drugs which have been banned in the country of origin".⁸ There were over sixty drug manufacturers with major percentage of foreign ownership. Under the new FERA regulations of the Government of India, fifty of these firms diluted their foreign equity to 40 per cent or below in order to be considered as Indian concerns and get all types of facilities. This is a fraud, as they have not diluted their foreign equity shares through public financial institutions but amongst themselves and their Indian collaborators. Over 60 per cent of the drug production and imports in India are under their direct and indirect control.

In the sphere of Drug production, marketing and distribution, only 30 per cent to 35 per cent are essential and life saving drugs, while non essential and useless or harmful drugs occupy 65 per cent of the total drug production. In 1979, the Government of India issued the Drug Price Control Order (DPCO) and categorised all the major formulations in four different categories. Category I & II are mostly essential drugs with 40 per cent and 55 per cent mark up respectively, category III and IV are mostly non-essential drugs with 100 per cent and above mark up respectively. The following table shows the increase in production in these four Categories after the DPCO :—

Category	Period	Percentage of rise in production
I (Life saving)	1979-80 to '83-84	5.28
II (Essential)	" "	6.89
III (Marginal)	" "	121.33
IV (Marginal)	" "	34.16

There were over 8000 drug manufacturing units in Indian in 1984-85 (most of them are small ones) including public sector units, multinational and national private sector units. Collectively they produced 2 per cent of the total world drug production for 18 per cent of the world's population, to tackle 24 per cent of the total world morbidity with only 0.6 per cent of world production of essential drugs. The Government, without specifying the quantum of essential and life saving drugs, fixed the Sixth Five Plan target for drug production at Rs.815 crores worth of bulk drugs and Rs.2450 crores worth of formulations, but by the end of Sixth Five Year Plan we find that the production of bulk drugs were worth Rs.405 crores in place of Rs.815 crores and that of formulations Rs.1837 crores in place of Rs.2450 crores.

Plan year of Sixth Five Year Plan	Production of bulk drugs (in crores of Rs.)	Production of formulations (in crores of Rs.)	Estimated production of essential drugs out of formu- lations (in crores of Rs.)
1980-81	255	1260	360
1981-82	289	1430	400
1982-83	323	1600	430
1983-84	345	1600	466
1984-85	405	1837	512

Steps to augment essential Drug production

The following steps should be taken to augment essential drug production to meet the need of primary health care by 2000 AD :

1. In the Sixth Five Year Plan period, the Government of India allotted Rs.400 crores only for drugs production, Rs.250 crores for the private sector and Rs.150 crores for the public sector. This was in spite of the fact that it was decided by the Government of India that "the public sector should take a leading role".⁹ With such poor allocation of funds the Public Sector can neither take a leading role nor fulfil production targets. The Government of India should revise its Seventh Five Year Plan allocation of funds on drugs to the tune of Rs.3000 crores at least to produce bulk drugs worth Rs.1,062 crores, formulations worth Rs.2,000 crores and

exports worth Rs.600 crores. The deployment of allocation should be as follows :

Public Sector	—	Rs. 1,750 crores
Small Sector	—	Rs. 750 crores
Private Sector	—	Rs. 500 crores

75 per cent of the entire allocation should be geared for production of essential drugs.

2. Similarly the Government shall have to invest Rs.5,000 crores and Rs.7,000 crores during the Eighth and Ninth Five Year Plans, respectively. By the end of the Ninth Five Year Plan, we need to produce Rs.16,000 crores worth of formulations including Rs.12,000 crores worth of essential drugs and Rs.6,000 crores worth of bulk drugs. These calculations are based on the assumption that the present rate of inflation, population rise etc., shall remain constant. The ultimate objective must be of nationalisation of the drug industry in phases.

3. There should not be any rise in markups on essential and life saving drugs, though upward revision has been suggested by the steering committee of the National Drugs and Pharmaceuticals Development Council. Production of these drugs should not be assessed on the basis of commercial viability. Defence of the health of the people should be considered at par with the national defence expenses and expenses on human resource development, if not more.

4. There are gross shortages of vital essential drugs to treat Malaria, Tuberculosis, Leprosy, Filariasis, Kalazar, Anaemia, Helminthic infections, Diarrhoeal and Enteric group of diseases, Immunising agents, etc. To meet the shortage in a short period, the Government should introduce incentives for production of essential drugs. 80 per cent of the production capacity of public sector units and 65 per cent for all types of private sector units should be geared to manufacture bulk drugs and essential and life saving drugs without exception. This demands determined political will of the Government in power at the Centre. The multinational units may be allowed to continue if they agree to deploy their production capacity as suggested above, are willing to transfer technology and are willing to dilute 75 per cent of their foreign equity shares through public sector financial institutions.

5. All essential drugs should be marketed by their generic names. There are about 3000 drugs being sold under 50,000 brand names. A sum of Rs. 250 crores was spent during 1984-85 alone to create brand images of these drugs and this amount is included in the price structure of the drugs. It has been said that Doctors often forget their forefathers' names in order to be able to remember these brand names.

6. All types of sales tax, octroi, excise duty, customs duty, surcharges etc. should be abolished for essential drugs, including bulk drugs required

for manufacturing essential drugs. It is gratifying to note that the Government of India recently made partial concession on some drug items but price hikes in other vital sectors will nullify the concessions.

7. Bulk drugs, canalised items and imports should not be diverted at the cost of essential drugs for production of profit oriented marginal or useless remedies.

8. Target for production of drugs should be set in terms of quantity, like it is done for other essential commodities. Setting targets in terms of monetary value is useless, for such targets are open to variations due to inflation and other vagaries of the commodity market.

9. Regional disbursement of drug industry; setting up of Research and Development laboratories in each zone; coordination within various departments of the Government; ensuring proper quality control and good manufacturing practices; developing self sufficiency in technical know-how; ensuring ethical and scientific dispensing habits and updating the prescribing habits of doctors; essential drug distribution through state or local body sponsored cooperatives; are some of the measures to be taken up without further delay.

10. A high power "Drug Authority of India" with proper legislative backing should be set up to control, monitor and supervise all aspects of "Drugs", namely, imports, production, price fixation, setting priority for essential drugs, allocation of bulk, drugs, manufacturing practices, storing, distribution, dispensing, drug testing, drug research and development, drug control, etc. This "Drug Authority of India" should have representatives from the States, professions (medical and pharmaceutical), and technologists from various related disciplines. Each State should also set up a "State Drug Authority" for overall monitoring of drugs, from manufacturer to consumer. The "Drug Authority of India" should work on the basis of guidelines formulated by the Hathi Committee and W.H.O., with scientific updating at regular intervals, with powers to revise Indian Pharmacopoeia and National Drug Formulary.

Drug Information

This has assumed very significant importance in view of the fact that a large number of prescriptions are found to be unscientific, unethical, unnecessary, saturated with excessive drugs in a single prescription, often leading to iatrogenic or adverse effect on health.

In several prescriptions bacteriostatic drugs have been prescribed with bactericidal drugs; B. complex with Sulpha drugs; Pencillin with Tetracycline and Metronidazole with high Alcoholic Tonics. In several prescriptions it has been noted that highly concentrated Vit. "B" complex or Vit. "C" has been prescribed to be taken for 5 to 6 months. In many prescriptions

Halogenated Quinoline group of anti-amoebic drugs have been prescribed continuously for 6 to 8 years causing neurotoxic effects. There are many such examples. About 20 per cent of people undergoing treatment with modern drugs suffer from iatrogenic (drug induced) diseases.

Training and teaching of pharmacology is not adequate in undergraduate courses. After graduation, drug retailers of the multinational and big national manufacturers become their modified pharmacological teachers. In most of the cases, doctors overtly or covertly become prescribing agents of multinational and big national drug manufacturers. The Companies in turn offer them plenty of free samples, attractive gifts and host lavish parties for them.

The Government of India and the State Governments with the concurrence of the Medical Council of India and with the help of Doctors' and Pharmacists' Associations should organise regular refresher courses through the medical teaching institutions to update their knowledge in various disciplines of medicine including pharmacology, in batches, every 2 or 3 years.

The Government through the "Drug Authority of India" should publish bimonthly or quarterly "Prescribers Journal of India" like in the U.K., U.S.A., and other advanced countries, with detailed information regarding drugs. This is very essential for generating scientific prescribing habits in Doctors and rational dispensing habits in pharmacists.

Concluding Remarks

It is necessary to launch a broad based movement with the active support of people hailing from all walks of life and socially motivated medical and paramedical personnel. Active involvement of all democratic mass organisations, and professional and scientific organizations needs to be sought in order to bring pressure upon the Government of India, to create a determined political will to ensure drugs for all by 2000 AD. □

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National Drug Policy — Viewed in the Context of Our Health Policy

(Dr.) Sujata Dhawale*

Factors Influencing Health

It is now widely acknowledged that there are certain very basic determinants of Health. Some of the principal factors that influence Health are as under :

1. Daily per capita Calorie supply as percentage of requirement
2. Percentage of population with access to safe drinking water
3. Adult Literacy Rate
4. Population per physician.

Unfortunately today, when one talks of Health, only curative measures, drugs and Doctors are regarded as important. This kind of a commercial approach to Health is a relatively recent phenomenon. Such an approach is, in fact, a feature of the society in which 'Profit Motive' is the driving force that determines all relations of production.

The crux of the problem is that a high level of medical technology cannot by itself promote Health. It is not the number of sophisticated hospitals or the extent of advanced research in modern medicine which rate among the principal factors influencing Health. In the ultimate analysis it is the socio-cultural and economic forces in a society which decisively influence the Health of the people. It is this point which one needs to bear in mind while analysing the Health Policy in India.

Neglect of Health Sector in India

It is evident that in India, even conceptually, Health is not recognised as a fundamental right. The Indian Government, due to its political compulsions, does not consider Health to be a priority sector — as investments in this sector do not bring in quick returns. That, it is part of

our Government's policy to treat Health as a low priority sector, is borne out by the following table :

Table I	
Health Budget in Successive Five Year Plans	
Plan Period	Per cent share of Health Budget
2nd Five Year Plan	3.30
3rd Five Year Plan	2.60
4th Five Year Plan	2.10
5th Five Year Plan	1.40
6th Five Year Plan	1.80

Further, the meagre resources allocated for Health are not equitably distributed. Health facilities as are available, are concentrated in urban centres and mostly cater to the upper strata of our society. Thus an overwhelming majority of our people are deprived of even the basic medical facilities. This lays them open to the onslaught of market forces — i.e., in the absence of a Health network, people are forced to 'buy' Health facilities in the market like any other commodity.

Drug Policy for Profit Motive

It is in this context that the National Drug Policy needs to be viewed. The National Drug Policy cannot exist in isolation of our Health Policy or the existing Health network. Thus, given our country's policy perspectives in the Health Sector, what we have as a Drug Policy is basically a pricing and production policy where the dominant force is the 'Profit Motive'. It is a policy which is heavily oriented towards the benefit of the multinational drug manufacturing companies, rather than the interests of the Indian people. That is why essential drug production in the country falls far below target levels while drug multinationals reap super-profits by producing useless and hazardous drugs. This explains why, when 50 lakh doses of polio vaccine are required, only one-tenth of the requirement is met, leaving the rest of the needy to their fate. It also explains why Vitamin A production in 1984 was only 50 per cent of the target, and yet simultaneously the assets of Multinationals in the drug industry have gone up from 10 crores in 1950 to 2000 crores in 1985.

Transnational Corporations' Stranglehold

Our National Drug Policy must aim at breaking the stranglehold of Transnational Companies on the Drug market. A target needs to be set whereby, after a stipulated time, all Transnational firms will be nationalised. This also underscores the immediate need for development of self sufficiency,

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which cannot be achieved but for a phased plan. In this we should point out the need to develop the indigenous systems of medicine which have originated from our country.

Thus the following issues need to be taken up on a priority basis.

1. Development of the indigenous systems of medicine (like Ayurveda etc.).
2. Development of the public sector Indian Pharmaceutical Industry.
3. Identification of national resources for the growth of indigenous productivity, leading to a self sufficient economy.
4. Successful absorption of manpower available in the country for the development of above objectives coupled with research and development.

Hazardous Drugs

The next important point without which the drug policy may be self defeating and, on the contrary, allow a wrong flow of drugs in the market, is the adoption of steps to ensure a ban on drugs introduced and sold in the Indian market which have been banned elsewhere. It is common knowledge that the developing countries are treated as dumps for drugs which may harm the Health of the people of Western Nations. In the process Transnational Companies amass profits, and test the real dangers and side effects of hazardous drugs on the people of developing countries. Many such drugs can be named which have had disastrous effect in the United States and have been banned there, yet various derivatives are manufactured and promoted in the developing countries.

For example Anabolic steroids (generic names) are widely used to stimulate growth in children and adults, but have been found to seriously hamper normal growth and, worse still, to virtually cause change of sex in female patients, (as claimed in Physicians' Desk Reference America 1983). Yet in our country, Rs. 50 crores worth of the drug is being freely marketed and heavily advertised, a far cry indeed from being banned! A total of over Rs. 500 crores worth of different kinds of hazardous drugs are sold in the Indian market.

Summing up this point, which at no cost must be underplayed, we demand :

1. A full tight check on all drugs being brought into the Indian market, with complete analytical picture of the effects, side effects etc., of each; control experiments conducted before routine use is promoted.
2. An in depth study of the history of the drugs coming in and whether or not they are still being used in the countries from where they originate.

3. Proper Committees of experts to supervise the same before issuing Licences.

This responsibility becomes all the more pressing as the lessons of the Bhopal gas tragedy surface on the national panorama and is talked about, criticised, and discussed. We have to remember that far more serious and silent dangers lurk in the very drugs that one takes to cure oneself of disease, and which instead destroy one's healthy existence. One should also remember that this poison will not destroy openly, neither will it hurt one or two individuals, nor will it hurt a single localised population; instead it will destroy a whole generation of our people.

Problem of Inessential and Irrational Drugs

Moreover the problem of ensuring adequate supply of essential drugs needs to be squarely faced. The drugs which are manufactured or are available in the market are more often than not inessential or not useful for tackling the major Health problems of our Country. For example, while Tuberculosis and Scabies are common diseases in our country, Drugs which are required for the treatment of the same are in short supply, whereas drugs necessary to reduce high blood pressure (anti Hypertensives) which are more relevant to developed nations where obesity is a problem; are freely available. In our Country their need is limited.

Further, most of the drugs which are available in the market have no balanced formulas i.e., the drugs are heavily loaded with extra doses and components in order to promote them against other products of the same type. The most glaring example of this problem can be seen at the Primary Health Centres run by the Government for the rural masses. While the Doctors shout themselves hoarse that they need basic drugs like Aspirin, and anti Tuberculous drugs etc., to run the Centres, they are supplied everything but these.

Coming to the second point, excess and unnecessary components are incorporated in the drugs, beyond the capacity of the body's mechanism to absorb them. Thus these components are ingested only to be excreted as can be seen in the case of the various B-Complex preparations available in the market. Vit C is required in normal healthy adults and children in the dose of 30 mg. Yet there are Vit C preparations which are promoted at a dose of 500 mg three times a day.!

Not only is this a financial burden for patients, but also it drains the country's economy, and around Rs. 1500 crores worth of such components literally go down the drain, taking along with them valuable foreign exchange (on irrational B-Complex preparations alone we lose Rs. 3

crores of foreign exchange). The rest of this financial drain occurs due to irrational use of tonics, nutrients, expectorants, Vitamins analgesics, tranquilisers, sedatives, antihistaminics etc.

The solutions therefore can be underlined thus :

1. A complete analysis of the diseases prevalent in the country, and related drug requirement blue-print.
2. A detailed study and an in depth consideration of the cost factors as related to the predominant diseases in the country and accordingly a channelisation of resources to draw maximum benefits for the maximum population at the lowest cost.
3. A strict regulation of the drug compositions which are manufactured and marketed so as to avoid wastage and economic drain.

Finally, it is necessary to suitably amend legislation relating to the Drug Industry. Minus such a step, it would be impossible to ensure any kind of control on the workings of the Drug Industry.

The above suggestions are by no means complete, in fact they fall short of the most important measure necessary for the successful implementation of any programme, viz., conscious and systematic effort to implement the same. No Drug policy or Health policy can be meaningful without the participation of the people. And therefore it rests on all our shoulders to see that such a movement is built up — a movement that will give the correct direction to the Drug policy, as the first step towards our goal.

Actual Drug Needs : Facts and Fallacies

(Dr) Shambhu Maitra *

Introduction

Drugs form a major part of the Health care delivery system today of almost every country in the world. They were a small appendage to the Health services less than 100 years ago but have now turned into the nucleus of the Health care delivery system. The basis of such a qualitative change, in short, is the ushering in of a commodity concept of Health with gradual erosion of the concept of public Health.

The realm of Health has come to be influenced by the change of orientation of our society with the octopus of commodity economy spreading its tentacles over Health services. Thus the very essence of community Health stands altered. With this commercialisation of Health, the profit-oriented pharmaceutical companies nowadays have infused the conviction into the minds of all and sundry that 'there is a pill for every ill' — with the help of their extensive propaganda machinery.

Drugs worth Rs. 100 million was consumed in India in 1947. In 1975-76 the figure rose to Rs. 10,500 million, and during the current year 1985-86 it is likely to exceed Rs. 20,000 million. Rising prices apart, this tremendous increase is due to increased production of drugs. The point in consideration, however, remains whether or not such a plethora of drugs is really essential and whether the long list of drugs India produces includes all that are needed for the Health care of its people.

My topic of discussion in this paper is 'Actual Drug Needs'. I propose to discuss this under the following five heads, keeping in mind the aforesaid political economy of Health :

- Whose needs ?
- Who determines the needs ?
- What are the needs ?
- Are drugs being produced as per needs ?
- Supposing drug production pattern is need based, how would drugs reach the people ?

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Whose Needs?

It is needless to say that needs are of the people afflicted with ailments, i.e., patients. However, the requirement and production of a commodity largely depends on the socio-economic status of the consumers. Before going into details, therefore, it is better to have an idea of the socio-economic conditions prevalent in India.

- INDIA — With 48 per cent of its people below the poverty line;
- With 84 per cent Health care costs being paid privately;
 - With only 20 per cent of Government Health Budget being spent on drugs;
 - With only 20 per cent of our people having access to modern medicine;
 - With 80 per cent of the drugs being available only from the private market and not through Government Health Services;
 - With only 32 per cent literacy rate and with much less having knowledge of English — the language in which drug information is usually given;
 - With over 50 per cent of drugs being sold over the counter without prescription;
 - With 45,000 formulations flooding our markets;
 - With rise in drug prices having occurred in spite of the price control order;
 - With further price hikes on the horizon.¹

Thus it can be stated that a majority of Indians do not and cannot have access to modern medicine in the present conditions. Further, this dismal picture will remain unaltered if the socio-economic conditions remain as they are today.

Moreover our pharmaceutical industry has developed on the lines of development of the industry in the Western World. Naturally, the pattern of drugs produced in India is considerably influenced by the pattern of diseases prevailing in those countries (where longevity is generally higher), where there is prominence of diseases of old age such as high blood pressure, heart diseases, cancer and degenerative diseases. On the other hand, in poor countries like India where longevity is considerably lower, those diseases are not as prominent, and the main causes of morbidity and mortality are diseases of poverty, viz., Gastro-enteritis, other water-borne diseases, diseases arising out of lack of preventive immunisation, or malnutrition, Tuberculosis, Leprosy etc. Similarly, the fact that the drug industry in India is in private hands which produces mainly for profit also results in a situation where the drugs required by the poor are not produced as there is no profitable market and adequate demand for them,

while the country continues to be flooded by a large number of costly and wasteful drugs meant for minor illnesses of the rich and the well-to-do.

Who Determines the Needs?

Drugs differ from other consumer goods in that while we ourselves choose consumer goods we need, we do not determine our need of drugs. We go by the doctor's advice. In the case of over-the-counter drugs too, we casually consult the men selling the drugs, though very few of them happen to be qualified pharmacists.

So it is the doctors who determine what drugs their patients would need. And it is the general belief, that all that the doctors prescribe are absolutely necessary. Our drug market has about 45,000 formulations of about 400 or so basic drugs.

However, the World Health Organisation (WHO) has noted that about 250 drugs would suffice to take care of almost all the ailments human beings suffer from. Further, according to the 'Hathi Committee' about 104 basic drugs would be sufficient for 95 per cent of the ailments Indians are afflicted with. So the conclusion one is forced to draw is that most of the drugs we are made to consume are not necessary for our ailments. Now, the question arises, why do doctors prescribe these useless drugs if they are not needed?

Medical students are trained in line with disease patterns and medical care prevalent in the West. They learn more of heart diseases, Cancer, etc., than under-nutrition, Gastro-enteritis, Malaria, Leprosy and Tuberculosis i.e., the diseases rampant in their own country. There is little scope to get acquainted with the life style of the people, their economic conditions and the socio-economic perspective. They are taught about drugs, but not the economics behind drugs. When they leave college as doctors, their subsequent training is taken up by the drug companies. They introduce the doctors to thousand-and-one brand names and convince them of the infallibility of their combination products which no text books approve of. This being so, the estimate of drug needs made by qualified doctors incline more towards the interests of the industry than towards that of patients.

While doctors determine the individual needs of their patients, there are a number of bodies set up by the Central Government to estimate the overall actual drug requirements of the country. It is astonishing to note that excepting the report of the Hathi Committee (which has been duly discarded) all the experts sing to the same tune. Their recommendations directly or indirectly help the drug industry to accumulate more profits without meeting the actual Health and Drug needs of the common people. Let me put forth a few examples in favour of this statement.

(a) The National Drug and Pharmaceutical Development Council (NDPDC) formed by the Ministry of Chemicals & Fertilisers constituted three working groups to study various aspects of drugs and pharmaceuticals and submit their report to NDPDC. The experts committee of NDPDC first selected 121 essential drugs, which included the following groups :

Antibiotics	19 drugs
Anti T.B.	4 drugs
Anti Malarials	5 drugs
Cardiovascular	22 drugs
Diuretics	11 drugs
Oral Contraceptive	10 drugs

It follows from this recommendation that Oral Contraceptives and drugs for Cardiovascular diseases are much more needed in our country than anti-T.B. drugs or Antibiotics respectively!²

(b) the same is reflected from the demand estimates drawn up by the Council :

Table 1³

Group	Unit	Estimated Production '84-'85	Estimated Demand '89-'90
1. Cardiovascular	T	29.21	112.45
2. Anti Malarials (2 Drugs)	T	440.00	725.00
3. Anti TB (5 Drugs)	T	778.00	1490.00
4. Phenylbutazone	T	112.85	220.00
5. Oxyphenbutazone	T	110.00	6650.00
6. Iodo-Chlorohydroxy-Quinoline	T	136.80	460.00
7. Di-iodohydroxy Quinoline	T	95.55	160.00
8. Analgin	T	849.71	1000.00
9. Vitamin B ₁₂	Kg	360.00	580.00

The above table shows a surprising affinity of our Government to the demands of Oxyphen/Phenylbutazones and also Clioquinolines which are now considered as dangerous drugs and have been banned in several countries.

(c) The NDPDC, in its 58-Page report has not uttered anything about withdrawal of banned and hazardous drugs.

(d) An essential drug list consisting of 104 drugs was drawn up by the Hathi Committee in 1975. The NDPDC steering committee reduced the number to 95 priority drugs in 1984. The decrease in number was motivated by an attempt on behalf of the drug industry to keep the drug price control basket as small as possible. Production of non-essential, irrational and even hazardous drugs has been made more remunerative by the drug pricing structure, leading to their proliferation.

What Are the Needs ?

These may be classified broadly as actual needs and created needs. The actual need of drugs is determined by the pattern of morbidity due to prevailing diseases and also the number of people vulnerable to the diseases. But unfortunately the criteria for assessing target demands by NDPDC is based mainly on past drug production and past growth trends rather than on present assessment of health problems and drug needs. NDPDC in its own report states :

"It may be observed that under present conditions because of lack of essential data, it is not possible to predict the requirement of individual drugs with sufficient accuracy. The committee relied on the following essential criteria for assessment of demand :

- Past trends of production of the drug.
- Past trends of import of the drug.
- Past actual annual growth rate and its total availability (Production + Imports - Exports) in comparison with those anticipated by the Sixth Plan working group on drugs and pharmaceuticals.
- Trends in growth rate of various formulations.
- Obsolescence of the drug and anticipated introduction of new drugs with less side reactions and better substitutes being available.
- Requirement of the drugs in National Health programmes.
- Anticipated export of bulk drugs and formulations".⁴

Except for (f), all the other criteria are based on past production, past growth trends and/or mere anticipation. The drug policy has based its drug production targets more on market demands than on Health demands. Health needs, service targets and Health demands - these three major criteria for estimation of drug requirement have not been taken into consideration at all.

This deficiency in recognising the actual demand of essential drugs is in sharp contrast to the created needs deliberately imposed by the vested interests. A product is manufactured and then by intensive sales promotion people are made to believe that the product is a necessity. Thus, market demand of a particular product is not a true index of its essentiality. This holds good in the case of drugs too. Chloramphenicol is an actual need in Enteric fever, whereas a multivitamin and a protein preparation which invariably go with it, are a created need. The following tables show the decreasing trend of production of essential drugs on one hand and the stepping up of more profitable nutritional supplements on the other.

Table 2⁵

Production of Domic Essential Drugs

Drugs	Unit	Total availability	
		82-83	83-84
1. Chloramphenicol	T	111.46	97.22
2. PAS & its Salts	T	288.44	216.99
3. INH	T	194.57	152.51
4. Piperazine Salts	T	86.90	53.45
5. Dapsone	T	65.64	42.47
6. Ampicillin	T	142.27	131.23
7. Penicillin	MMU	360.82	332.66
8. Sulphadimidine	T	513.90	480.60
9. Chloroquine	T	280.55	142.94

Table 3⁶

Production of Some Immunological Agents

Drug	Unit	Total availability	
		82-83	83-84
1. Triple Vaccine	KL	18.96	18.85
2. Tetanus antitoxin	MUZ	16,155.01	11,011.79
3. Diphtheria antitoxin	MU	653.57	568.38

Table 4⁷

Pfizer's Production Figures

Drug	Unit	Licensed capacity	1980	1981	1982
PAS	T	110	23.80	13.78	5.70
INH	T	80	73.77	54.00	71.57
Protinex	T	110	254.86	252.15	278.79

Another example of the distorted planning priorities is depicted in the following table which gives the mid-term appraisal of demand estimate of bulk drugs as given in the NDPDC report. It shows no demand increase in INH and PAS, between 1985 and 1989, in spite of the common knowledge that the overall number of T.B. patients is increasing. On the other hand, for controversial drugs like Hydroxy-quinolines and Oxyphenbutazones, the annual increase in target demands shown over the same years is significant.

Table 5⁸

Drug	Unit	84-85	85-86	86-87	87-88	88-89	89-90
INH	T	250	250	250	250	250	250
PAS & its Salts	T	270	270	270	270	270	270
Iodochlorohydroxy-quinoline	T	230	280	330	400	480	572
Di-iodo Hydroxy-quinoline	T	280	310	340	380	416	460
Oxyphenbutazone	T	110	125	145	165	190	220

Are Drugs Being Produced as per Needs?

The answer to this question is *NO*. The following table is self explanatory. essential drugs required for the National Health Programmes like T.B./Malaria/Filaria/Blindness control/immunisation programmes/ Leprosy, and some drugs needed for diseases having greater morbidity, severe sequelae etc., have been considered in this table :

Table 6⁹

Name Name Name	Unit	1982-83		1983-84	
		Demand		Total	
		Unit	Demand	Demand	Total
		Unit	Estimate	Estimate	Availability
1. Penicillin	MMU		370	560.32	390
2. Streptomycin	T		270	247.87	270
3. Chloramphenicol	T		300	111.46	300
4. Ampicillin	T		200	142.27	240
5. Sulphadimidine	T		600	513.90	630
6. Sulphadiazine	T		100	106.10	105
7. Vitamin A	MMU		77	52.00	90
8. PAS & its Salts	T		80	72.84	90
9. INH	T		250	288.4	250
10. Chloroquine	T		200	194.57	240
11. Piperazine Salts	T		335	280.55	350
12. DDS (Dapsone)	T		200	86.90	210
13. Diethyl Carbamazone	T		70	65.64	60
14. Triple Vaccine	KL		20	18.96	21
15. Tetanus Anti Toxin	MU		13000	16155.01	13000
16. Diphtheria Anti Toxin	MU		800	653.57	800

In spite of this wide disparity between demand and availability, nothing has been done to check it. On the contrary the measures adopted by the Central Government is becoming more and more beneficial for the drug industry to earn more profits. Non-essential, irrational and hazardous drugs are being produced in abundance. The policy makers are very keen

to help the multinational companies, whereas the public sector is incurring heavy loss every year.

Table-7¹⁰

Profit & Loss of Public Sector

Name	Net Profit (+) / Net Loss (-) Rs. in Lacs		
	82-83	83-84	84-85
1. I.D.P.L.	(-)2401	(-)1943	(-)2628
2. Hindustan Antibiotics	(-) 23.87	(-) 171.41	(-) 498.00
Bengal Chemical & Pharmaceuticals	(-) 282.50	427.00	(-) 540.00
4. Bengal Immunity	(-) 338.85	(-) 376.71	(-) 199.00
5. Smith Stanistreet Pharmaceutical Ltd	(-) 27.21	(-) 11.70	(+) 1.50
			(-) 427.00

Table-8¹¹

Cross-section of Multinational Companies

Name	Country of origin	Sales in crores of Rs.		Growth per cent
		1979	1984	
1. Glaxo	U.K.	35.10	54.55	55.41
2. Sarabhai	U.S.	33.59	51.34	52.84
	collaboration			
3. Pfizer	U.S.A.	28.93	40.65	40.57
4. Hoechst	F.R.G.	17.45	33.16	90.03
5. Burroughs Wellcome	U.K.	13.51	26.74	97.92
6. Boots	U.K.	12.14	25.14	111.45
7. German Remedies	F.R.G.	10.53	19.25	88.81
8. Parke Davis	U.S.A.	11.85	18.90	59.50
9. S.G.Chemicals	Swiss	11.69	17.90	53.12
	collaboration			
10. May & Baker	France	9.89	17.50	77.30
11. SKF	U.S.A.	8.23	17.15	108.38
12. E. MERCK	F.R.G.	8.50	16.65	95.88
13. Warner	U.S.A.	9.72	15.50	59.57

One of the most important features of any drug is its quality. As admitted by the Government itself 20 per cent of all drugs produced in this country are substandard and spurious. Substandard and spurious drugs are produced by all sectors including multinational companies as shown by the fact that in 1980, 135 samples of substandard drugs were from 23 MNCs out of a total of 218 cases.

There are approximately 8000 formulators producing 45,000 formulations in the country. It is impossible to expect from the Indian Drug Control (Quality) authorities to ensure good manufacturing practices and quality of drugs with the help of only 600 drug inspectors and five quality testing laboratories. So, not only is the production of essential drugs far less than the targets (which are estimated empirically and unscientifically) but the drugs produced are often substandard. On an average, one out of every five medicines we buy, is ineffective and at times dangerous.

If Drug Production Pattern Is Need-based How Would These Reach the People?

Let us suppose that after very careful and rational consideration an accurate demand estimate of drugs is made and these are adequately manufactured with strict quality control. Are these going to reach the common people who need them? Unfortunately, the answer is not in the affirmative. Ours is a country where millions of people die of poverty. Unemployment has become a common feature of every house. The increase in our gross national income has remained only a statistical reality, where the rich become richer and the poor become poorer. Thus mere increase in drug production and availability cannot ensure supply of drugs to all those who are in need of them. For this, it will be necessary to increase the paying capacity of our common people. This will be possible only if sweeping socio-economic changes are initiated. The slogan of 'Health for All by 2000 AD' can be realized only if the Health Movement becomes an integral part of the broader movement for changing the socio-economic structure of our country.

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Essential Drugs Concept, Need and Implementation

(Dr.) Mira Shiva*

"The acceptance of the idea that a limited number of drugs can cater to over 90 per cent of the pathological problems in developing countries has, with one bold stroke, swept away the very carefully cultivated (and promoted at high cost), the often spurious, justifications for the large number of brand named drugs. Now the list is short. The choice is clear. If it is not made, it is either the result of ignorance or inability to face the pressures of pharmaceutical interests".¹

Concept of Essential Drugs

The concept of Essential Drugs was arrived at for helping policy makers, health personnel, the industry and the consumers differentiate clearly between drug demands created by market forces as opposed to genuine drug needs. The two fundamental principles related to the concept of Essential Drugs are :

1. The selection of drugs should be based upon established health needs, not simply upon professional or public demands.
2. Priorities for selection should be established by and be consistent with the national health policy.

The WHO Expert Committee on Essential Drugs attempted to provide guidelines to the member countries in drawing up a national list of essential drugs. "It is clear that for the optimal use of limited financial resources the available drugs must be restricted to those proven to be therapeutically effective, to have acceptable safety and to satisfy the health needs of the population. The selected drugs are here called 'essential' drugs, indicating that they are of the utmost importance, and are basic, indispensable and necessary for the health needs of the population".

Further, according to WHO, "Essential Drugs" are those that satisfy the health care needs of the majority of the population.

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"Since the launching of WHO's action programme for essential drugs in 1981, more than 80 countries have either drawn up essential drug lists or started projects in support of primary health care, providing reliable essential drugs and vaccines which :

Meet Real Medical Need : This means that their use is likely to improve the quality or extent of medical care.

Have Significant Therapeutic Value : This means that they must do what is claimed for them, and that patients will benefit from that.

Be Acceptably Safe : This means that their likely benefits must far outweigh risks.

Offer Satisfactory Value For Money : This favours the introduction and use of drugs which work as well as other medicines, but cost less".²

Thus, the basis of any national drug policy must be based on rational selection of drugs and this selection must have medico social justification such as :

- Therapeutic Efficacy
- Safety
- Cost of total course of Drug Treatment, not merely Unit cost of a Drug
- Ease of Administration
- Limited potential for misuse
- Indigenous production
- Ease of transport, storage
- Long shelf life

While dealing with the issue of essential drugs it is important to differentiate between Rational, Essential and Priority Drug lists. This is important, since the Essential Drugs concept entails withdrawal of drugs that are irrational and hazardous. While it would be preferable to have mainly essential drugs available in the private as well as the public drug market — till the concept is properly understood — the drugs in the market should at least be rational drugs.

Rational Drugs are those drugs which are accepted worldwide and included in the standard text books of medicine and pharmacology.

Essential Drugs are those selected by each country according to health needs of its people, based on well defined criteria, e.g., Norway has based the selection of essential drugs on "efficacy", "safety" and "Medical Need".

Priority Drugs List is drawn from among the essential drug list to give priority to drug production, distribution and availability for use in diseases having :

- greater mortality (death)
- greater morbidity (illness)
- severe sequelae (after effects)
- communicability (e.g T.B., Leprosy)

and for use in national programmes such as T.B. and Malaria eradication, Blindness control, Goitre control, Immunization etc.

Graded Essential Drug List. This constitutes selected drug lists drawn up for different levels of health institutions, depending upon the competence of health personnel, diagnostic, referral and specialist services available, the disease pattern in the area etc. For example Bangladesh has drawn up graded essential drug list for village health workers, at thana and district levels, along with a supplementary list for specialists.

Medical Need Clause. In Norway, the usage of the medical need clause precludes the registration of any new drug which is not more effective than one that is already in use, and which is not safer and cheaper than drugs currently used.

National List of Essential Drugs : According to UNCTAD, identification of essential drugs and formulation of a national drug list is the most important aspect of an integrated rational drug policy.

The WHO Committee on selection of essential drugs suggests that not only specialists in clinical medicine and pharmacology but also general practitioners and other health workers should be consulted. The advice of pharmacists is specially valuable on dosage forms, packaging and distribution problems. The national list should be reviewed every 2-3 years.

The essential drug lists may be divided into sub-lists in the following manner :—

1. Drugs to be sold without prescription i.e., Over-the-Counter-Drugs.
2. Drugs constituting about 10% of the essential drugs distributed commercially, comprising mainly of drugs meant for symptomatic and prophylactic use.
3. Drugs reserved for general hospitals and for practising physicians.
4. Drugs reserved for highly specialised hospitals. This sub-list should be restricted to conditions specifically requiring them.
5. Sub-list of vital drugs (life saving drugs). Such vital drugs are needed by patients to maintain life e.g., insulin, digoxin etc. It is important that their supply must never be interrupted.³

Enforcement of the Exclusive use of Essential Drugs

Although it may be possible to enforce the exclusive use of essential drugs in the public health services sector, this has not been generally

attempted seriously in countries with a private pharmaceutical sector. Unless essential drugs are used in the private as well as in the public sector, an essential drug policy will not succeed.

"What is at issue here is less a question of which drugs are on whose lists, rather than one of who has access to what list and whose prescribing is bound by none."⁴

For the essential drug movement to be successful, a wide range of inter-related issues need to be addressed — these include :

- definition of what drugs are most cost-effective in terms of treating the more prevalent conditions;
- the need for separate essential drug lists for different level of health care;
- efficient and timely procurement systems;
- efficient distribution systems;
- an effective drug management system to ensure reasonable ordering and supply of drugs to where they are needed, and when they are required;
- reasonable prescribing practices;
- adequate information for patients in relation to the prescribed treatment;
- measures to encourage patient compliance with prescribed drugs;
- public health education regarding the benefit and limitations of drug treatment.⁵

Besides the above, the following aspects must also be taken care of :

- Formulation and wide utilization of a National Drug Formulary
 - to provide Therapeutic Guidelines
 - to provide cost comparison of treatment course;
- ensuring of quality control of the drugs in the market;
- appropriate training of health personnel in selection and usage of rational drugs to upgrade competence and expertise;
- collection of epidemiological data to monitor the disease pattern in the area and to select the kind of drugs needed and also to set realistic target demands.

The Need

With increasing pharmaceuticalization of health care, health care is unfortunately being equated with more and more consumption of drugs. This has led not merely to warping of the concept of health care and to spiralling costs of medical care, but has created ample room for socially

sanctioned exploitation. The Government of India's National Health Policy statement of 1982 acknowledges that : "the imported and inappropriate model of health services is too heavy, over centralized, heavily curative in its approach, urban and elite oriented, costly and dependency creating".

The ICSSR, ICMR Expert Committee, "Health for All : Alternative Strategy", 1981, commenting on such a model stated that "A linear expansion of this model and the consequent pumping of more funds into the system will merely add to the existing waste and make the ultimate solution of our health problems more difficult".

We have failed not merely to turn our attention to longer lasting health solutions that deal effectively with the roots of ill health, but we have failed to ensure rationality even in the curative care which has become a substitute for comprehensive health care.

Annexure I shows that 84 per cent of expenditure on health care is paid for privately by the people. The average expenditure on drugs is said to be Rs. 26/- per capita. With around 50 per cent of our people below the poverty line, such per capita expenditure is significant.

This concept of Essential drugs is not limited to more formulation of the essential drug list or its pricing, it means ensuring of adequate production, streamlined distribution, easy accessibility, affordability and availability of selected essential drugs with accompanying unbiased drug information. It is unbelievable that almost nine years after WHO brought its first Technical Report Series on selection of essential drugs in 1977, many of our policy makers, doctors and officials are still not familiar with the content and the spirit of this important document which in many ways has been a paradigm shifter for many.

The concept of essential drugs is integrally linked up with the concept of Primary Health Care. If the spirit of the Alma Ata Charter of 1978 of which India is signatory is not understood and implemented, the concept of essential drugs will have no meaning. The demand for both is interlinked, and in essence it is a demand for social justice in health care. (See appendix 2 — Alma Ata Charter)

Need for Drug Limitation

There is an urgent need to withdraw from the world market, specially in the developing world, drugs that are known to be irrational, hazardous, unduly expensive and with no therapeutic advantage. This would include majority of the combination drugs, with very few exceptions.

An extract from the UNCTAD document, "Guidelines on Technology issues in Pharmaceutical sector in the developing countries, major elements of an integrated pharmaceutical policy" highlights just this :

"Limiting number of drugs: The average doctor has repertoire of perhaps 30-40 drugs prescribed regularly and another 50 or so used occasionally. There is no evidence, that a large number of drugs improves health care. On the contrary it is known to increase the incidence of unwanted effects. The accountability of so many different drugs, and the use of similar names for different drugs, or of different names for similar drugs, entails dangers for public health as well as a tremendous waste of effort and money. From the public health standpoint, it creates and/or increases the chances of error in the prescription or absorption of drugs and results in the inadequate treatment of patients and an increased incidence of adverse effects.

The abundance of medicines furthermore, taxes both the memory and the working capacities of personnel in charge of distribution and control of the use of medicines. Again, the availability of more than one medicament for a given purpose increases the cost of imports, manufacture, formulation packaging, storing and distribution. Small quantities of a large number of items are more expensive to handle than large quantities of a few items.

In the light of experience in both developed and developing countries, it is now generally accepted that the number of drugs necessary for treating a large majority of diseases is relatively small. Only drugs that are necessary or useful for treatment of identified health problems should be allowed to be sold. The number of available medicines should thus be limited in rich and poor countries alike not only for budgetary reasons but also for the protection of health against inappropriate medication."

Implementing Essential Drugs Concept

The need for selection of essential drugs was experienced long before WHO stated it in its Technical Report Series 615 in 1977. Most of the initiatives came from the Third World. People like Dr. Allende, Dr. Seneka Bible and Dr. Zafrullah Chowdhury will undoubtedly go down in history for their role in promoting The New Pharmaceutical Order based on the essential drugs concept.

Chile — In 1971 Dr. Salvador Allende, a socially conscious medical doctor by profession, during his brief tenure as President of Chile attempted to rationalise his country's drug policy by restricting imports, sales and prescription of useless and irrational drugs, and by giving priority to essential drugs.

Amongst the first to be exterminated with the taking over by the Junta, besides him, were the medical doctors who had dared to dream of a

rational drug policy based on essential drug concept for their country.

Sri Lanka — In 1972 Sri Lanka reduced the number of imported drugs from 2100 to 600 by removing all unsafe and cost ineffective drugs from its private market. Dr. Seneka Bible played a key role in this.

Mozambique — In 1975 with the liberation of Mozambique, a new law was passed based on the concept of essential drugs. A decision to re-register all products was taken and the government's desire to see mainly essential drugs in the market was stressed. A reduction in the number of formulations from 13,000 to 2,600 was brought about by this measure.

The number was further decreased to 430 by 1977 and to 343 by 1980. This led to decrease in drug prices upto 1/3 of their original price and no change in drug import costs from that of 10 years ago.

A National drug formulary was drawn up to provide therapeutic guideline and unbiased drug information to the doctors.

"In 1981 four years after the publication of National Drug Formulary based on Essential Drugs a study of 4000 prescriptions showed that 83 per cent of all prescriptions were in accordance with the National Drug Formulary and only 5 per cent brand names were used."⁷

India — In 1975 In India the Hathi Committee recommended the withdrawal of irrational drugs and prioritization in production and distribution of 116 selected essential drugs. Due to lack of political will, neither of these was implemented, nor was easy availability of essential drugs, even for the national priority programmes, fully ensured — despite possessing the capability of doing so.

Afghanistan — In 1977 Afghanistan decided to decrease the number of drugs from over 2000 to 400 in private as well as public sector. All drugs were sold under generic names.

Iran — In 1980 Iran decided to exclude several combinations and inessential drugs, bringing down the number of drugs in the market from 4000 brand name products to 600 active substances in 1000 prescription forms to be sold under generic names.

This number of selected essential drugs is applicable for public as well as private sector. Today about 70 per cent of all prescription carry generic names.

Bangladesh — In June 1982 Bangladesh passed a Drug Ordinance based on WHO's concept of Essential Drug list.

The two major components of this Essential Drugs Policy consisted of, first, screening of over 4000 drugs in the market and withdrawal of 1742 drugs. The second was identification of 150 selected essential drugs which were graded into 3 categories based on location of utilization and level of potential users.

The graded Essential Drug List constituted of the following :

1. 12 Essential drugs selected for village level health workers
2. Additional 33 Essential drugs for Primary Health Care to Thana Health Complex level.
3. Additional 105 Essential drugs for use at tertiary level. An additional supplementary list of 76 drugs to be increased upto 100 was drawn up for restricted use by specialists.

The Bangladesh experience has been hailed the world over as a courageous, trail blazing effort at rationalizing its drug policy. It has proved that Third World countries can evolve and implement rational drug policies guided by the concept of Essential drugs, even in a country like Bangladesh with over 80 per cent dependence on foreign aid.

Table - I
PRICES OF SOME RAW MATERIALS BEFORE
AND AFTER ORDINANCE (US \$ / Kg)

<i>Raw Material</i>	<i>Before Ordinance</i>	<i>After Ordinance</i>
Tetracycline HCl	75	28
Oxytetracycline HCl	80	30
Ampicillin	120	60
Amoxycillin trihydrate	40	66
Cloxacillin sodium	115	72
Doxycycline HCl	1250	250
Trimethoprim	150	46
Glibenclamide	2350	150
Hyoscine-N-butylbromide	1358	830

Table - II
MAXIMUM RETAIL PRICES OF SOME ESSENTIAL
DRUGS BEFORE AND AFTER ORDINANCE
(TAKA PER CAPSULE OR TABLET)

<i>Raw Material</i>	<i>Before Ordinance</i>	<i>After Ordinance</i>
Ampicillin 250 mg	2.00	1.50
Tetracycline 250 mg	1.04	0.70
Co-trimoxazole	2.30	1.15
Amoxycillin	3.50	2.35
Metronidazole 400 mg	1.42	0.85

It also proves that such a policy can have very far reaching results for the Nation and its people. The following have been the principal gains of the Bangladesh Drug Ordinance :—

1. Ensuring of production, distribution and availability of Essential drugs by the Government health infrastructure.
2. Non-rise, if not fall, in drug prices (See Tables).⁸
3. Withdrawal of 1742 irrational and hazardous drugs.
4. All new drugs registered have been strictly in keeping with the Nation's Essential Drug List and Essential Drugs concept.
5. Annual turn-over of the drug industry has shown an increase with no multinationals leaving Bangladesh.

Kenya — Based on WHO's Essential Drugs concept and the country's morbidity pattern, Kenya has drawn up a list of 40 essential drugs for its health centres and 30 essential drugs for its dispensaries. A list of 200 drugs is provided to the Government Institutions.

The above system, backed by streamlining of drug distribution, standardization of drug treatment schedules and training of health personnel has ensured availability of essential and life saving drugs to 80 per cent of Kenya's population.⁹

WHO's Essential Drugs concept is relevant not merely for developing countries but for developed countries as well. If the efforts of Bangladesh, Mozambique etc., at rationalizing their drug policy are being projected by vested interests as legitimizing of second class medicines in half starved or starving poverty stricken Third World countries, then attention must be focused on Scandinavian countries. Their stand regarding essential drugs is illustrative.

Norway — In Norway, the criteria currently used for the selection of drugs is as follows :

- selection should be based on scientific documentation;
- the efficacy/toxicity ratio must be weighed against the severity of the disease;
- new drugs should be more effective than those already in the market;
- drug combinations should be avoided unless they show a clear advantage over the use of each ingredient separately;
- there should be a clear cut medical need for any new product;
- the number of drugs should be limited.

Between 1981-83 the Specialities Board rejected approximately 46 per cent of applications for registration of new products. Of these 60 per cent were rejected on consideration of need. The following Table shows how successful the efforts of Nordic countries have been in limiting the number of formulations.

Table - III

**NUMBER OF REGISTERED PHARMACEUTICALS IN THE
NORDIC COUNTRIES — JANUARY 1980**

<i>Country</i>	<i>Brand Names</i>	<i>Dosage forms & strengths</i>
Denmark	2201	3824
Finland	Not available	3594
Iceland	728	1164
Norway	1058	1986
Sweden	1418	2432

Further the Norwegian policy in respect of fixed ration combinations has been based on the following principles :

- each component should make a contribution to the effect claimed;
- a component may be added to enhance the effectiveness or safety of the active ingredient or to minimize potential abuse of this ingredient;
- the components should have approximately the same half life and duration of action

In addition a patient population of reasonable size should benefit from the combinations.

Norwegian drug registration policy has demonstrated over a number of years that it is possible to restrict the number of drugs on the market quite appreciably without any adverse effect on patients.¹⁰

Operation Sabotage

The resistance to the Essential drugs concept, and national policies based on it, has come chiefly from the drug industry and their bureaucratic sympathizers and some members of the medical establishment whose relationship with the drug industry is increasingly being questioned worldwide. It is with great vengeance that effort is being made to puncture the growing acceptance of the Essential drugs concept.

Nationalist feelings of the Governments are being evoked. At least at two forums, i.e., in Nairobi at the Conference of Experts on Rational Drug Use and in the World Health Assembly in Geneva this year, the WHO has been forced to state that it is not a supranational body; hence has no real power over the powerful pharmaceutical lobby and cannot force any international codes of conduct as regards ethical marketing practices.

Pressure by U.S. Administration

Certain documents produced by the Heritage Foundation, the right wing think tank of the Reagan administration, indicate clearly the threats being faced by WHO. The two documents "WHO Resists Third World Ideological Pressure" and "WHO — the moment of truth" make nauseating reading.

The withdrawal by USA of 6 per cent of its contribution to WHO with a threat to walk out of WHO along with the 25 per cent of the latter's annual budget, which is being contributed by USA, indicates that unlike earlier times, WHO's role in these critical areas is not being appreciated and will be strongly discouraged.

This became clear in this year's World Health Assembly (1986), where it was clearly indicated to WHO that its interference in the area of pharmaceuticals, baby food and tobacco would not be tolerated. It should also be noted that at the World Health Assembly in 1984, USA was the only country which had voted against the Nordic Resolution. The resolution was aimed at making efforts towards rational drug use worldwide, with WHO playing an important role.

In the first "Schwartz Commentary", which was carried in the drug industry's SCRIP magazine, the threat potential of a consumer lobby represented in WHO by Health Action International was pointed out. The European Pharmaceutical industry counterparts were also chided for not having taken a bold stand against the Nordic Resolution.

Attempt to Malign Bangladesh Drug Policy

Courageous efforts in Bangladesh at rationalizing its drug policy based on Essential drugs has led the Pharmaceutical Manufacturers' Association of USA to sponsor a WHO Consultant from an Asian country (in his individual capacity) to prepare a report with the purpose of proving that initiatives like the Bangladeshi drug policy do not work and how it has "not made the slightest dent in Bangladesh and how the problems associated with Bangladesh Drug Policy should not be repeated in other third world countries".¹¹

While on the one hand WHO's role is being challenged with direct attacks being made at Dr Ernest Lauridson, the courageous Program Coordinator of WHO's "Action Program for Essential Drugs", systematic efforts are being made to misrepresent the concept and build opposition towards its wide acceptance.

Attempts successful, and not so successful, are being made to 'buy' journalists, medical associations and consumer bodies. Attempts to woo the medical establishment are being made, with the industry encouraging the doctors' "right to prescribe" and "maintenance of clinical freedom".

Any attempt at rationalising selection of drugs is made out to be "restriction of clinical freedom".

Situation in India

This is ridiculous in a country like India where there is no restriction or monitoring of medical practice, and no system of ongoing medical education or drug information dissemination system. Here drugs can be prescribed and dispensed by qualified as well as unqualified personnel. Over 50 per cent of the drugs are bought over the counter without prescription, without drug information, and without consumer caution, in a society which is largely illiterate. Therapeutic guidelines are desperately required and so are inputs in medical education on rational drug use.

Just as some of the medical associations have excelled in their partnership with the drug industry in several ways including holding of academic conferences sponsored by the industry, the "real consumer associations" constituting associations of cancer and heart patients sponsored by the industry are meant to counter the increasing criticism and demand for change being raised by consumer bodies.

The industry does realize that the concept of essential drugs is a very powerful concept and sooner or later the national government, for economic, social and therapeutic reasons, will adopt it. An all out effort to restrict it to government health infrastructure is thus being made, so as to leave the private drug market untouched. This was repeatedly stated by the industry representatives at the Nairobi conference. Knowing fully well that over 80 per cent of drug consumption is through the private drug market, leaving it uncontrolled in a situation where government health services are failing to meet even the much needed basic health services will only help to make matters worse.

A country like India, with such a well developed drug industry and a large pool of trained medical personnel, cannot be excused for neglecting its people in terms of health care.

The role of 'Medical-Industry Complex' must be guided by health needs. Its contribution is needed, but the nature of it must be specified. Just as an ever increasing 'Military Industrial Complex' cannot ensure peace for the people, so also unrestricted growth of the drug industry and its products can never ensure health of the people.

Essential drugs concept puts health needs of the people first. Right across the world, the implications of the concept are being realised by the socially conscious health personnel who unfortunately constitute a minority. People all over the world, cutting across geographical, political and ideological barriers are beginning to join hands so as to understand and demand social justice in health care. This is what the Alma Ata Charter and the Essential drugs concept are all about.

APPENDIX-1

PRIVATE HEALTH CARE SPENDING IN SELECTED DEVELOPING COUNTRIES

<i>Countries</i>	<i>Private spending as percentage of total</i>
Afghanistan	88
Bangladesh	86
Botswana	16
Egypt	41
Ghana	72
Honduras	63
India	84
Pakistan	63
Philippines	79
South Korea	84
Sri Lanka	40
Sudan	41
Thiland	66

Source :Report of a WHO meeting on Drug Policies and Management
Procurement and Financing of Essential Drugs, No. DAP/84.5

APPENDIX-2

Declaration of Alma-Ata

The International Conference on Primary Health Care, meeting in Alma-Ata this twelfth day of September in the year Nineteen hundred and seventy-eight, expressing the need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world, hereby makes the following Declaration :

1. The conference strongly reaffirms that health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment

01 the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.

2. The existing gross inequality in the health status of the people, particularly between developed and developing countries as well as within countries, is politically, socially and economically unacceptable and is, therefore, of common concern to all countries.

3. Economic and social development, based on a New International Economic Order, is of basic importance to the fullest attainment of health for all and to the reduction of the gap between the health status on the developing and developed countries. The promotion and protection of the health of the people is essential to sustained economic and social development and contributes to a better quality of life and to world peace.

4. The people have the right and duty to participate individually and collectively in the planning and implementation of their health care.

5. Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures. A main social target of governments, international organizations and the whole world community in the coming decades should be the attainment by all peoples of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life. Primary health care is the key to attaining this target as part of development in the spirit of social justice.

6. Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.

7. Primary health care :

(i) reflects and evolves from the economic conditions and socio-cultural

and political characteristics of the country and its communities, and is based on the application of the relevant results of social, biomedical and health services research and public health experience.

(ii) addresses the main health problems in the community, providing promotive, preventive, curative, and rehabilitative services accordingly;

(iii) includes at least : education concerning prevailing health problems and the methods of preventing and controlling them, promotion of food supply and proper nutrition, an adequate supply of safe water and basic sanitation, maternal and child health care, including family planning, immunization against the major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs;

(iv) Involves, in addition to the health sector, all related sectors and aspects of national and community development in particular agriculture, animal husbandry, food, industry, education, housing, public works, communications and other sectors; and demands the coordinated efforts of all those sectors;

(v) requires and promotes maximum community and individual self-reliance and participation in the planning, organization, operation and control of primary health care, making fullest use of local, national and other available resources, and to this end develops through appropriate education the ability of communities to participate.

(vi) should be sustained by integrated, functional and mutually-supportive referral systems, leading to the progressive improvement of comprehensive health care for all, and giving priority to those most in need;

(vii) relies, at local and referral levels, on health workers, including physicians, nurses, midwives, auxiliaries and community workers as applicable, as well as traditional practitioners as needed, suitably trained socially and technically to work as a health team and to respond to the expressed health needs of the community.

8. All governments should formulate national policies, strategies and plans of action to launch and sustain primary health care as part of a comprehensive national health system and in coordination with other sectors. To this end, it will be necessary to exercise political will, to mobilize the country's resources and to use available external resources rationally.

9. All countries should cooperate in a spirit of partnership and service to ensure primary health care for all people since the attainment of health by people in any one country directly concerns and benefits every other country. In this context the joint WHO/UNICEF report on primary health care constitutes a solid basis for the further development and operation of primary health care throughout the world.

10. An acceptable level of health for all the people of the world by the year 2000 can be attained through a fuller and better use of the world's resources, a considerable part of which is now spent on armaments and military conflicts. A genuine policy of independence, peace, detente and disarmament could and should release additional resources that could well be devoted to peaceful aims and in particular to the acceleration of social and economic development of which primary health care, as an essential part, should be allotted its proper share.

The International Conference on Primary Health Care calls for urgent and effective national and international action to develop and implement primary health care throughout the world and particularly in developing countries in a spirit of technical cooperation and in keeping with a New International Economic Order. It urges governments, WHO and UNICEF, and other international organizations, as well as multilateral and bilateral agencies, non-governmental organizations, funding agencies, all health workers and the whole world community to support national and international commitment to primary health care and to channel increased technical and financial support to it, particularly in developing countries. The Conference calls on all the aforementioned to collaborate in introducing, developing and maintaining primary health care in accordance with the spirit and content of this Declaration.

APPENDIX-3

Example of a Drug List Structured by Therapeutic Category and Level-of-Use

Therapeutic Category	Level-of-Use			
	Community Health Workers	Dispen- saries	Health Centers	Hospitals
A. ANESTHETICS				
Anesthetic ether		x		x
Halothane		x		x
Sodium pentothal		x		x
Lidocaine		x		x
B. ANALGESICS				
Aspirin	x	x		x
Codeine		x		x
C. GASTROINTESTINAL PREPARATIONS				
Hyoscyamine sulfate	x	x		x
Magnesium trisilicate	x	x		x
Mineral oil		x		x

D. ANTI-ALLERGICS				
Diphenhydramine		x	x	x
E. SEDATIVES				
Diazepam (injectable)			x	x
Phenobarbital		x	x	x
F. ANTI-PARASITICS				
Metronidazole			x	x
Mebendazole			x	x
Piperazine	x	x	x	x
G. ANTI-TUBERCULARS				
Isoniazid			x	x
H. ANTI-MALARIALS				
Chloroquine phosphate (capsules)	x	x	x	x
Chloroquine phosphate (injectable)			x	x
I. ANTIBIOTICS				
Penicillin (tablets and suspension)		x	x	x
Penicillin (procaine and benzathine)			x	x
Triple sulfa tablets		x	x	x
Chloramphenicol (tablets and suspension)			x	x
Tetracycline syrup			x	x
J. VITAMINS AND MINERALS				
Multivitamins with folate and iron (capsules and liquid)	x	x	x	x
Ferrous sulfate (capsules and liquid)	x	x	x	x
Vitamin A	x	x	x	x
Vitamin K			x	x
K. RESPIRATORY SYSTEM MEDICATIONS				
Phenylephrine		x	x	x
Epinephrine			x	x
Aminophylline		x	x	x
L. OPHTHALMIC PREPARATIONS				
Silver nitrate		x	x	x
Sulfacetamide solution	x	x	x	x
Tetracycline ointment		x	x	x
M. DERMATOLOGICAL PREPARATIONS				
Gentian violet	x	x	x	x
Benzyl benzoate		x	x	x
Calamine lotion	x	x	x	x
N. CARDIAC AND ANTI-HYPERTENSIVE MEDICATIONS				
Epinephrine			x	x
Digitoxin			x	x
Reserpine		x	x	x
Chlorthiazide			x	x
O. HORMONES				
Insulin (regular)			x	x
Cortisone (injectable)			x	x
P. OXYTOCICS				
Ergometrine maleate			x	x
Q. BLOOD SUBSTITUTES				
Dextran			x	x

R. ELECTROLYTE SOLUTIONS

Oral rehydration packets	x	x	x	x
5% Dextrose			x	x
Lactated ringers			x	x
Normal saline			x	x

S. VACCINES AND IMMUNOLOGICALS

Antitetanus serum			x	x
DPT		x	x	x
Tetanus		x	x	x
Polio		x	x	x
Rubeola		x	x	x

T. CONTRACEPTIVES

Oral contraceptive tablets		x	x	x
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Source : Management Sciences for Health, Boston, USA.

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Hazardous Drugs and Their Promotion — History and Present Status

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Introduction

Medical Science has made tremendous progress in the recent past. The growth and development of the drug industry is perhaps one of the most important contributory factors.

There is no substance known which if ingested does not produce ill effects. A prolonged excess of common salt is known to be associated with Hypertension. A compulsive high intake of water is well known to cause water metabolism derangement. Who would call salt and water poisons? Yet even such innocuous substances have adverse effects. All medicines are poisons in certain amounts and the margin of safety between the doses needed for required action and that which produces adverse effects, is what determines the 'hazards of a drug'.

Factors Governing Adverse Effects

Factors governing the adverse effects of drugs include :

(a) *Non drug factors :*

- (i) Intrinsic to the patient : age, sex, genetics, allergy, disease and personality.
- (ii) Extrinsic to the patient : the prescriber or the environment.

(b) *Drug Factors :*

- (i) Intrinsic to the drug : side effects; Secondary effects like vitamin B-6 deficiency in INH therapy; Toxicity (due to over dose).
- (ii) Choice of the drug.
- (iii) Use of the drug (technique).
- (iv) Interaction between drugs.

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Further, drugs may interfere with the development of the foetus in the following manner :—

- (a) By directly interfering with enzyme and protein synthesis etc.
- (b) Indirectly : on the placenta
on the uterus
on the mother's hormonal balance
on the father's spermatozoon.

In this paper we shall limit our discussion only to the 'drug factors' which determine the hazardous effects of a drug. To someone uninitiated to the ways of functioning of the drug industry, it is often difficult to understand why drugs with known adverse effects continue to be marketed. Here, it is necessary to understand that all drugs produce adverse effects. Hence the decision on whether a drug should be promoted is dependent on whether the useful actions of a drug outweigh its adverse effects and whether a safer alternative is available.

However it would be naive to conclude that only these considerations are involved. In the drug industry the motive which overrides all other factors is the profit motive. Thus to satisfy their lust for profit, the drug companies are known to suppress information and even resort to blatant falsehoods to promote many hazardous products whose usefulness does not outweigh the hazards involved. To understand the extent and manner in which this is done, it would be helpful to go through the case studies of two such drugs.

The Thalidomide Story :

Thalidomide was a new drug introduced by the German Company, Chemie Grunenthal, in November 1956, as an *Antimicrobial* against respiratory infections. In October 1957, the same drug was introduced as a sedative! In 1958, a massive publicity campaign was launched for the promotion of the drug. 200,000 letters were distributed among doctors and 50,000 'therapeutic circulars' were sent to doctors and pharmacists. Cold, cough, flu, nervousness, neuralgia, migraine, other headaches, asthma, diarrhoea, name almost any common ailment and Thalidomide was said to form a part of the therapy for it. It became so popular for sedating children that it came to be called 'West Germany's baby sitter'. Moreover it was extensively promoted as a sedative for pregnant women.

Thalidomide crosses frontiers :

When a drug becomes popular it crosses frontiers. Soon Thalidomide was being sold by licences in eleven European countries, seven African, seventeen Asian, and eleven countries of the Western Hemisphere.

In addition to the parent company, Chemie Grunenthal, many other companies started marketing the drug viz., The Distillers Company Ltd., Great Britain; William S Merrell Co. Ltd., Canada; Astra., Sweden; Frank W. Horner Co. Ltd., Canada; Laboratorio FRC, Italy; Livsa, Italy; Lab. Peyta, Italy; Smit, Italy; Profarmi, Italy; Perkins Chemical Co., Italy; and Biorfa, Italy; to name a few.

The drug was sold in the West German market without any prescription. In promotional literature for Thalidomide special stress was placed on the complete safety of the drug. 161,916 copies of a circular distributed in West Germany alone read, 'The substance . . . babies is so atoxic that it can be administered even to new born babies and infants'. In August 1958, 40,245 letters were sent to different physicians describing it as the 'best drug for pregnancy' which does not damage either mother or child. A printed matter showed a child climbing up to a cupboard and opening a Thalidomide bottle. The printed matter included : 'This child's life may depend on the safety of Distaval (Thalidomide)'.

Evidence of Neurotoxicity

In 1956 and 1957 many cases of loss of balance and giddiness were reported as side effects of Thalidomide. The company ascribed these side effects to overdosage and prolonged use. In August 1959 the company referred to, in print, occasional side effects as 'drowsiness next day' and a 'moderate tendency to constipation'. The other effects were considered as 'rare' and 'very seldom observed'. On 3 October 1959 a written report was received from a Neurologist. The company was asked whether anything was known about Contergan (Thalidomide) causing damage to the peripheral nervous system. The company stated that such effects had never been observed. This was a lie. Damage to the peripheral nervous system had been reported in clinical trials by the company in 1956, in a report by a doctor in Aug. 1958 and by a company salesman in July 1959. On 15th October 1959, another doctor was informed similarly. More such reports gathered in November 1959.

Massive campaign to 'cover up'

The company's policy at that time (as found in documents discovered later) could be thus summarised :—

1. To deny all casual connections between Thalidomide and Polyneuritis.
2. If there was no possibility of denying that Thalidomide had caused nerve damage then :—
 - (a) to associate the nerve damage with allergic factors.
 - (b) to minimise the severity of Polyneuritis.
 - (c) to withhold information about the true number of cases which were known to the company.

- (d) to ascribe rumours of Neurotoxicity to slander campaigns from the competitors.
- (e) to cause confusion as to the real nature of the damage.

On 15 February 1961, several typical cases of Neurotoxicity were presented at a Neurological meet. In March 1961, as a counter, the company started making notes on the private lives of physicians involved in the campaign against Thalidomide, and their families. One report said: 'The father of Dr. B is an ex-communist and nowadays a member of SED'.

By May 1961, the company had received 1300 reports of Neurotoxicity alone. Involuntary twitching of the facial muscles, tremors, abnormal sensations, speech and visual disturbances, severe disturbances of concentration, and even frank convulsions were noted. The effect in most patients was irreversible. The company directed that 'everything must be done to avoid prescription enforcement' since already a sizable amount of the sale was over the counter.

Publication of articles on hazards of Thalidomide were obstructed by the company. In December 1960, the company sent two of its doctors to plead with the concerned minister that the attack (against Thalidomide) was unjustified, and no side effects were known which could be connected with Contergan (Thalidomide). One salesman wrote 'My happy laughter and appropriate references to the completely harmless properties of the drug were apparently successful'. Moreover Grunenthal resorted to denigration of the scientists and floated rumours doubting their competence.

By September, 1961, the reports of nerve damage exceeded 2400. The true number was even concealed from the company's partners abroad. The company went to the extent of attempting to involve an eminent Neurologist, who was campaigning against Thalidomide, in a 'sex scandal'. However the worst was yet to come.

Phocomelia

Phocomelia means 'seal extremities'. This unusual congenital deformity, where babies are born with grossly deformed seal-like limbs, was not reported in any clinic in the Federal Republic of Germany between 1949 and 1958. In 1959, 17 cases, in 1960, 126; and in 1961, 477 cases were reported. Similar sharp rise in the number of such cases were reported from Japan, Sweden, Britain, Italy, Spain etc.

The cause of this epidemic of phocomelia was troubling medical men. In July 1961, Chemie Grunenthal was asked whether Thalidomide was safe for use in pregnancy. The company and its collaborators had not conducted any research in this regard till then. The company however maintained that the drug was safe in pregnancy.

In November 1961, a Pediatrician presented 34 cases of phocomelia. He

suggested that 'a' drug could be the cause. Soon after the meeting, he was asked whether it was Contergan (Thalidomide). Several letters followed with a similar question because many of the physicians were personally involved. This was so because many of their wives had taken Contergan (or other forms of Thalidomide) and had given birth to abnormal babies.

The latter half of November 1961 saw hectic developments in the company. The Medical Director of the company was informed, but he did not pay any attention to the facts told to him by a Pediatrician. The company on the contrary described the issue as 'murdering a drug by spreading rumours'. Along with this the company sent 66,957 copies of letters to practitioners stating 'Contergan is a safe drug'.

On 26 November an article appeared in a Daily Newspaper, 'Welt am Sonntag', entitled 'Pharmacological Bomb'. Afraid of the public opinion created by the news, the company was 'forced to withdraw the drug from the market' (as written to its collaborators abroad.) After withdrawal of Thalidomide there was a sharp decline in the cases of phocomelia. Confirmatory evidence that Thalidomide caused the epidemic of phocomelia can never be obtained. But there is no doubt that it did cause it. This is evident from the graph showing the close relation between phocomelia and the sale of Thalidomide.

The Clioquinol Story

CIBA laboratories started manufacturing this compound in the beginning of this Century. By 1913 it was already being marketed on the other side of the globe in Japan, as a topical agent. In 1930 it was being promoted for diarrhoea and dysentery as Enterovioform tablets. Soon it was also being used for prophylaxis against diarrhoeas.

Interestingly, toxicity of Halogenated quinolines (a group of drugs which includes Clioquinol) was recorded as far back as in 1875. In 1935, two cases of neurological complications in man was reported from Argentina. In 1939 CIBA conducted animal trials which showed drug induced convulsions in dogs. Animals had an unsteady gait and appeared 'Dazed'. Neurotoxic effects were also noted in chicken embryos, mice and frogs. In 1958 a Swiss veterinary specialist found Neurological problems in cats and dogs and published it in 1965. Similar reports came from Sweden.

However, by 1964 total sales of Halogenated quinoline drugs reached the staggering figure of 1000 tons per year. The manufacturers continued to claim, even in the absence of any evidence, that it was not significantly absorbed when taken orally, to cause any systemic adverse effects. It was clearly shown, later in 1975, that Clioquinol was significantly absorbed and it accumulated in the body. It continued to be present in a concentration of 10mg/dl one month after stopping treatment.

Clioquinol in Japan and SMON

Japan's case is most illustrative. In the later half of the sixties, 40 to 44 tons of Clioquinol was produced in Japan yearly, in addition to imports. In 1957 eight regional epidemics of an hitherto unknown Neurological disease was recorded. In May 1964, at the 61st General Meeting of the Japanese Society of Internal Medicine, the condition was named SMON (Subacute Myelo Optic Neuropathy).

Clinically SMON had the following features :

1. Abdominal : Diarrhoea, pain abdomen, nausea, vomiting, constipation and bloated feeling of abdomen.
2. Neurological symptoms (indicating involvement of eyes, brain, spinal cord and nerves) : These were either acute or subacute in onset. Bilateral ascending sensory loss, with sensory symptoms in the form of tingling numbness and feeling of walking on pebbles. The loss of sensation was for touch, deep touch and proprioception.

Some of the more serious observed effects included motor paraparesis (partial paralysis of lower limbs) of spastic type (Pyramidal signs positive) and bladder and bowel disturbances. Upper limbs were also affected but less often (Hoffman' sign positive). 20 to 40 per cent of cases affected had visual disturbances ranging from slight blurring of vision to blindness. Convulsions, consciousness disturbances, disturbances of speech and swallowing, giddiness, and involuntary movements were also seen in some cases. All cases had nervousness, depression and/or insomnia. Examination of blood and cerebrospinal fluid showed no abnormality.

In 1961 a total of 60 cases of SMON were reported in Japan. In 1966 the total number increased to 1859. In 1967 alone 1452 new cases were reported while incidence rose to 1770 in 1968 and 2340 in 1969. Most patients were elderly. 90 per cent were significantly affected. 75 per cent had weakness of both lower limbs while more than 10 per cent were completely bed ridden. Total blindness was noted in 2.5 per cent and bladder and bowel paralysis in 4 per cent of cases.

Clioquinol implicated in SMON :

Many theories, for explaining the causes of SMON, were postulated. Familial occurrence, doctor/hospital centred epidemics, more incidence amongst medicos, and maximum incidence in late summer made people think of many causes. These included Vitamin deficiency, hereditary factors, and viral infection. It was even claimed that the causative Virus had been isolated.

The breakthrough came when Clioquinol was isolated from the tongue, faeces, and urine of all patients affected with SMON. Later in the same year Clioquinol was clearly implicated as the causative agent of SMON.

An incidence of more than 10 per cent was observed when more than 600 mg of the drug was taken for more than 2 weeks. (Each tablet is 300 mg, and recommended dose is two tablets thrice a day).

Sale of Clioquinol in Japan was prohibited on 8 September 1970 and no new cases were reported after 1971. More than a hundred cases of SMON have been recorded (all outside Japan) since the 1970s including nine published cases of SMON in India.

Continued production of Clioquinol

Strangely enough, Halogenated quinoline drugs continue to be extensively marketed in many countries of the world, especially in the Third World. This is all the more strange as there is now mounting evidence that these drugs are not only useless for treating diarrhoeal disorders but may at times aggravate the condition. CIBA-GEIGY has withdrawn its products, Mexaform and Enterovioform, from the world market due to pressures in its parent country but many other companies continue to sell the drug. In fact production of this group of drugs in India rose from 230 tonnes in 1979-80 to 365 tonnes in 1982-83!

Numerous instances of suppression of information :

There are many similarities between the two case studies. Both were avoidable diasters (and in the case of Clioquinol still is). The respective companies knew about the adverse effects of the drug concerned. But they valued profit more than human lives and deliberately suppressed information.

Many multinational drug companies have been involved in drug rackets of this sort. Some illustrative examples are given below.

T. Troch, a West German Company, once introduced a radioactive material, Peteosthor for the treatment of Tuberculosis. Later it was found that 19 of 53 cases treated with it died of bone cancer in 14 years!

Hoechst introduced Spirocid, an organic arsenic, for Congenital Syphilis, at a time when Pencillin was available in the market. It was however, promoted and was subsequently found to produce encephalitis, Spastic paraparesis, atrophy of muscles, brain atrophy and mental retardation! Eight years after the publication of the adverse effects of the drug, the company continued to promote it as a 'Tonic'!

The Indian Market — Plethora of 'hazardous drugs'

India is patently representative of the kind of anarchy which prevails in the drug market of most Third World countries. The market is replete with a plethora of useless, irrational, and most important, hazardous

drugs. Given below is a brief discussion of some of the major hazardous drugs available in the Indian market. The list is in no way exhaustive but includes those products which need to be weeded out or severely restricted on a priority basis.

1. Halogenated Quinoline group of drugs

Indications for which promoted : Intestinal amoebiasis, Bacillary dysentery, non-specific diarrhoeal disorders.

Reasons for banning : The drugs have been found to be associated with a condition called SMON (for details refer to earlier pages). Further there is evidence that the drug is often useless for treating the conditions mentioned and may even aggravate the condition.

Safer alternatives : Tinidazole, Metronidazole, Chloroquine and Dialoxonide Furoate in Amoebiasis. Co-trimoxazole in Bacillary dysentery. For most types of Bacillary diarrhoea and viral diarrhoeas oral rehydration therapy (intravenous fluids in severe cases) is the first choice for treatment.

Countries in which banned or sales restricted : Denmark, Dominican Republic, Italy, Norway, Japan, Nepal, Phillipines, Saudi Arabia, Sweden, Venezuela, Bangladesh and Cyprus.

Common Brand Names (as single drug or in combination) : Alliquin Forte, Amicline, Amicline Plus, Chlorambin, Diodoquin, Nivembin, Enteroquinol, Quiniodochlor, Dysfur Plus, Stadmed Entrozyme, Entrozyme, etc.

2. High doze Estrogen Progesterone Combination (EP Forte) Drugs

Indications for which promoted : The group of drugs was initially promoted for pregnancy testing in 'Sixties'. However, evidence gathered that these drugs can lead to birth of deformed babies if taken during pregnancy. Further, the test was found to give a 'false positive' result in 20 per cent of cases. These drugs were subsequently banned for use in pregnancy testing.

Now the drug is promoted for use in Dysfunctional Uterine Bleeding (DUB), Secondary Amenorrhoea, Dysmenorrhoea, Threatened and Habitual abortions.

In India these drugs are misused for inducing abortions and for pregnancy testing. This continues in spite of the fact that they are useless for inducing abortions (the irrationality of its use for pregnancy testing has been mentioned above). Major portion of the sales of these drugs takes place over the counter. Thus a large number of pregnant women continue to be exposed to this dangerous drug.

Reasons for banning : These drugs cause deformities in babies born to mothers who have taken these drugs during pregnancy. In addition if they

are taken by women who are not pregnant they may cause delay in menses.

Safer Alternatives : Both DUB and Sec. Amenorrhoea cases need to be thoroughly investigated and only a small percentage of these will require hormonal therapy. For those who require hormonal therapy, drugs which are indicated are either cyclical use of Estrogen and Progesterone separately, or Oral Contraceptive 'pills'.

For Dysomenorrhoea usually, the only therapy required is electrolyte and fluid restriction or antispasmodics. If hormonal therapy is required, drug of choice is Oral Contraceptive 'pills'.

For threatened and habitual abortions, if there is no organic problem involved, only treatment indicated is rest (No drugs are usually indicated — hormonal or otherwise)

Total Sales Turnovers : Rs. 5.38 crores in 1984.

Countries in which banned or restricted : Germany (FRG), Denmark, Saudi Arabia, Venezuela, Bangladesh, Italy, Austria, Belgium, Britain, Greece, Norway, New Zealand, Singapore, Thailand, U.S.A., South Africa.

Popular Brand Names : Disecron Forte, EP Forte, Menstrogen, Menstrogen Forte, Mixogen, Orasecron Forte, Orgalutin, Oestrone, etc.

3. Anabolic Steroids

Indications for which promoted : Breast cancer osteoporosis, pre- or post-operative debility, burns, uremia, aplastic anaemia, stimulation of growth in children, as general tonics (often in association with Vitamins).

Reasons for restricting use : Anabolic Steroids are indicated for all the above conditions except as growth stimulants and tonics. However, they are used principally in India for these two conditions. Infar India produces a formulation, 'Orabolin drops', for children. The British National Formulary specifically states "... the use of anabolic steroids as body builders and tonics is quite unjustified".

In young children they can cause early closure of epiphyses resulting in stunted growth. In boys they cause precocious sexual development and in girls can cause deformity of external genitalia. They can have a virilizing effect on women which may include baldness, deepening of voice, hirsutism (excess body hair) and can also cause menstrual irregularities. They can also cause liver tumors, salt and water retention, and alterations in Glucose Tolerance test and Thyroid Function tests.

Thus these drugs need to be *totally banned* for use on children. Besides, their use needs to be severely restricted, so that they are not used as general tonics and growth stimulants (the two major indications for which they are promoted today). Further, combinations of these drugs with Vitamins need to be totally banned.

Safer Alternatives : Modern medicine does not recognise the word 'Tonic'.

Specific deficiency disorders require specific therapy viz., Ferrous Sulphate in Iron deficiency, etc. For conditions like 'weakness', 'malaise' or 'fatigue', the only treatment required is a 'balanced diet', unless there is an organic cause.

Children do not require any 'growth stimulants' other than balanced diet, healthy environment and a healthy social milieu. If in spite of this, a child fails to thrive, then it needs to be investigated for some organic disease. In Menopausal Osteoporosis, Oestrogen is equally effective.
Total Sales Turnover : Rs. 10.01 crores in 1984-85.

Countries in which banned or restricted : Bangladesh has totally banned. In many other countries promoted only for specific indications.

Popular Brand Names : Anabolex B-12, Durabolin, Evabolin, Neurobol-H, Orabolin, Orabolin drops, Trinergic, Unabol, etc

4. Analgin and related drugs :

Indications for which promoted : Pain, inflammation and fever.

Reasons for banning : Analgin can cause a fatal disorder called agranulocytosis where the production of white blood cells in the bone marrow is suppressed.

It can also aggravate bleeding tendencies or prothrombin deficiency.

Safer Alternatives : For pain and inflammation, Aspirin, Ibuprofen and Indomethacin. For fever and pain, Paracetamol and Aspirin.

Total Sales Turnover : Rs. 17.02 crores in 1983

Countries where banned, restricted or not available : Australia, FRG, Denmark, Egypt, Israel, Italy, Mexico, Norway, Peru, Phillipines, Saudi Arabia, Sweden, U.S.A. Venezuela.

Popular Brand Names (as single drug or in combination) : Analgin, Avafortan, Baralgin, Novalgin, Novalgin-quinine, Pamagine, Ultragin, Esgipyrine, Oxalgin, Spasmizol, Spasmolysin, Buscopan-compoition, Zimalgin, etc.

5. Phenylbutazone and Oxyphenbutozone

Indications for which promoted : Pain, inflammation and fever.

Reasons for banning : Can cause a fatal blood disorder called agranulocytosis. Also known to cause kidney and liver damage.

Safer Alternatives : For pain and inflammation, Aspirin, Ibuprofen and Indomethacin. For fever and pain, Paracetamol and Aspirin.

Countries where banned or restricted : Argentina, Britain, Ireland, Israel, Phillipines.

Popular Brand Names : Betaflam, Buta-Proxyvon, Flamar-P, Jagril, Maxigesic, Parvon Forte, Suganril, Esgipyrin, Zolandin, Zolandin Alka, etc.

6. Chloramphenicol with Streptomycin

Indications for which promoted : Infective diarrhoea and Bacillary dysentery.

Reasons for banning : Chloromycetin (Chloramphenicol) is a drug with serious side effects — it leads to bone marrow depression in some, resulting in reduced white blood cell production, which may be fatal. Thus it should be reserved only for serious infections for which there are no equally effective alternatives, like in Typhoid fever. Streptomycin also has serious side effects viz., it can cause nerve deafness (It was thought earlier that oral Streptomycin is not absorbed at all, but this is not true).

Further, indiscriminate use of Streptomycin and Chloromycetin leads to drug resistance and hence their use in conditions where they are most required, i.e., Streptomycin in Tuberculosis and Chloromycetin in Enteric fever, gets limited.

Finally the combination is irrational. Chloromycetin is not useful in Salmonella gastroenteritis and in fact may prolong carrier state. Streptomycin resistance has developed in most cases of infections due to Shigella and other Enteropathogenic organisms.

Safer alternatives available : A majority (about 70 per cent) of diarrhoeal diseases are self limiting. Only treatment required is oral rehydration therapy (or intravenous fluids where dehydration is severe). In those requiring antibiotics, the drug of choice is Co-trimoxazole, Ampicillin or Gentamycin in fulminant cases.

Countries where banned : Bangladesh. In most countries this combination drug was never allowed to be marketed.

Popular Brand Names : Chlorostrep, Streptoparaxin, Intestostrep, Enterostrep, Streptochlor, etc.

7. Fixed dose combination of Streptomycin and Pencillin

Indications for which promoted : As a broad spectrum antibiotic.

Reason for banning : Streptomycin is still the most cost effective drug which is highly effective against Tuberculosis. Indiscriminate use of Streptomycin for all kinds of infections given rise to drug resistance, thereby restricting its use in Tuberculosis. Further, continued production of this combination means diversion of valuable quantities of Streptomycin (which is in short supply) which could be used to combat Tuberculosis.

Safer alternatives available : Broad spectrum antibiotics like Ampicillin, Amoxycillin, Co-Trimoxazole, etc.

Urgent Remedial Measures Necessary

Thus, from the limited number of examples cited, it is apparent that total anarchy prevails in the Indian Drug market. The market is full of drugs which pose a potent threat to the health of millions. If this dangerous situation is to be reversed, certain urgent steps need to be taken, e.g.

1. The National Drug Formulary needs to be periodically updated. This has not been done since 1979. Updating should be done at least annually.
2. All the drugs being sold in the Indian market under various brand names need to be identified. These should then be scrutinised by an Expert Committee. All drugs found to be unsuitable should be immediately taken off the market. Necessary changes should be made in the Drug Legislative machinery to expedite this process.
3. The Government should take up the responsibility of providing unbiased, scientific drug information to doctors and chemists. This can take the form of a periodical publication with regularly updated information. Such a step shall drastically reduce the dependence on biased drug information provided by the Drug companies.

The steps listed are not really difficult to implement. All that is required is the necessary political will. At stake is something so vitally important that even a short delay can mean risking the lives of thousands.

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Irrational Drugs And Irrational Drug-Combinations

(Dr.) Anant R. S.*

Introduction

Irrational drug may be defined as one which is either not proved to be therapeutically useful or is too toxic for the benefit it renders and for which there are better substitutes available. Irrational drug-combination is one which consists of at least one such irrational drug or an irrational combination of two or more rational drugs in which combining the drugs neither increases the efficacy nor reduces the dose or toxicity. We are not including here the irrational use of rational drugs. For example use of vitamins to gain strength; or female sex hormones to prevent abortions.

In terms of quantity, the problem of irrational drug-combinations is many many times more than the problem of irrational drugs, there being literally hundreds of irrational drug-combinations. Irrational drugs (useless or hazardous drugs) also pose an important problem. Let us first deal briefly with the problem of irrational drugs and then that of irrational drug-combinations. We will briefly deal with only prominent examples since it is not the purpose of this paper to give a complete and exhaustive account of this phenomenon.

Irrational drugs

There are many drugs which become obsolete either because new evidence emerges about their being not useful, or being too toxic, or because better substitutes become available. But many drug companies continue to market such drugs for years together even after medical authorities have declared them to be obsolete. Today, many such obsolete, irrational drugs are being marketed. We would briefly illustrate a few prominent examples.

Analgin : (Famous brand — Novalgin) This painkiller, also known as matamizol or dipyrone, can cause amongst other things, agranulocytosis —

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a life-threatening blood disorder; and in view of availability of better substitutes, it has been banned or withdrawn from sale in Australia, Seeden, U.K. and Bangladesh; is not available in the U.S.A., and left for very limited indications in Japan, Philippines, Denmark. But it is being rampantly used in India.

Amidopyrine : Another painkiller it is similar to Analgin in its toxicity and has been banned by the Government of India but was still available in the market for quite some time after this ban order of 23rd July, 1983. Even today, you may occasionally get this drug in the market in a combination form under some fancy brand name.

Butazones : Phenylbutazone and its breakdown product in the body, Oxyphenbutazone, are very powerful anti-inflammatory and analgesic drugs. But they very frequently lead to serious, even life-threatening side effects ".... poorly tolerated by many patients some type of side effect is noted in 10 – 45 per cent of patients and medication may have to be discontinued in their cases."² Some of the side effects are life-threatening and hundreds of deaths have been reported. According to Dr. Sidney Wolfe : "the full number number of worldwide deaths of all kinds from these two drugs is approximately 10,400. The fact that Ciba-Geigy has reports of 1182 is quite consistent with often mentioned statistics that only one out of ten adverse drug reactions which occur are actually reported by doctors."³ In view of the fatal side effects and the fact that equally effective, yet safer substitutes (Ibuprofen, Indomethacin) are now available, these butazones have been withdrawn in a number of countries viz., United Kingdom, Norway, Israel, Jordan, U.A.E., Zimbabwe, Baharain, Bangladesh.⁴

The Clioquinols : Well-known brands like Intestopan, Mexaform, Enterovioform etc., used in the treatment of diarrhoea contain Clioquinol group of drugs. This group can cause a deadly disease called SMON – Subacute Myelo-Optic Neuropathy – characterized by paralysis of legs and partial or total blindness. In Japan, more than 10,000 persons were struck by SMON and the Tokyo District Court implicated Clioquinol and its producer Ciba-Geigy for it. Though these cases occurred after two weeks or more of treatment with Clioquinol, lower dosages are not safe either. Hence Clioquinols have either been withdrawn or banned in a number of countries. In India and similar countries, Clioquinols have been widely (mis) used for all types of diarrhoeas. However, its effectiveness has been scientifically established only in cases of Intestinal Amoebiasis. It is not the drug of choice even for this condition. Diloxanide Furoate is now-a-days preferred. The only advantage of Clioquinols is that they are much cheaper. But it is possible to reduce the price of Diloxanide Furoate by adopting some specific measures and hence it is practicable to ban Clioquinols altogether without adversely affecting the poor patients.

Anabolic Steroids : These drugs are promoted by the drug industry in India for the treatment of "growth-failure loss of appetite and weight, wasting disease, in convalescence" etc. None of the medical textbooks recommend this group of drugs for any of these conditions. These drugs have hazardous side effects like distorted sexual development, premature closure of epiphyses and hence stunted height in children; liver and kidney damage etc. In the Western countries, they are used for certain rare disorders. Methyl Testosterone can be used in these rare disorders and hence in a country like India where, today, it is not possible to restrict its use to only such rare conditions, it is best to ban these drugs altogether.

Miscellaneous ingredients in tonics : These ingredients are by and large not harmful, but they are unnecessary and useless. For example, use of Glycerophosphates in tonics has no validity. "The use of expensive preparation of organic phosphates as tonics has no validity."⁵ Similarly addition of minerals like Manganese, Zinc, or even Copper has no validity. "There is no evidence that copper ever needs to be added to a normal diet either prophylactically or therapeutically."⁶ The American Medical Association's "Drug Evaluations" advises that in multivitamin preparations "additional components, such as liver, yeast and wheat germ do not confer any special advantage over the pure chemical ingredients, and inclusion of agents that have no proved value (e.g. Choline, methionine, levithin, bioflaronoids, inositol) is unwarranted."⁷

Cyproheptadine ("Periactin") and Pizotifen ("Mosegor"): These antihistaminics (popularly known as "antiallergic" drugs) are promoted by drug companies as appetite stimulants. But medical authorities deplore such use because in most cases there is some underlying cause which must be treated. In the third world countries, generally the underlying cause is lack of proper food and/or infection. Secondly according to the AMA Drug Evaluations "although the results of several studies suggest that Cyproheptadine stimulates linear growth and weight in children, this effect is inconsistent, transient, and quickly reversible after withdrawal of the drug."⁸ This is true for Pizotifen also.⁹

Pectin, Kaolin : Used in almost all antidiarrhoeal preparations, (famous brand – Pectokab) these agents have not been proved to be useful. On the contrary, there is some evidence that they interfere with the absorption of antibiotics and oral-rehydration solution and hence standard medical authorities now-a-days deprecate use of these agents. But in India almost every patient treated for diarrhoea gets some Pectin and Kaolin!

Guicolates Creosates & other 'expectorants' : Included in all so-called expectorant mixtures, their value has not been proved and has been questioned. Recent editions of standard medical textbooks do not recommend these irrational drugs.

This list of useless or toxic drugs is not at all comprehensive, but is sufficient to give an idea about the nature of the problem.

Apart from the above old, obsolete drugs, there are many *new irrational drugs*. This category of drugs is promoted as significant advances over already existing drugs without adequate scientific basis of its superior efficacy or safety. Sometimes they are promoted (especially in the third-world) even when the company knows that its claims are not true! Let us see a couple of recent classic examples of such unscientific drugs.

Glafenine : This new painkiller is sold by the German multi-national — Hoechst — under the brand name Glifanan. Withdrawn in Germany in 1983 for anaphylatic allergic reactions, kidney and liver damage, in the third world countries it is advertised as “ideal, pure analgesic” and “tomorrow’s analgesic.”¹⁰

Chymotrypsin : Yet another, anti-inflammatory drug not recommended by medical textbooks is being promoted in India (by Lyka Labs, for example — as Alfapsin) for “Plastic surgery, Vascular surgery, ENT Surgery, Oncology, bronchopulmonary disorders ...” etc. The British National Formulary says that “Their therapeutic effectiveness is doubtful.” The famous Laurence’s textbook of Pharmacology says that “Given orally, both enzymes (Trypsin and Chymotrypsin) are probably useless for alleviating inflammation, haematomas and bruising, though extensive claims are made”¹¹

NET-EN : Nor-Ethisterone-Enanthate is a long-acting injectable hormonal contraceptive which is sought to be introduced into India’s Family Planning programme. It has not yet been proved to be safe. Animal studies have indicated development of cancer due to this drug. There are no well designed sufficiently long-term studies to answer such questions raised by the studies made so far.¹² This drug has a number of troublesome side effects and being injectable, it will definitely be misused extensively in the high-pressure Family Planning programme and would, therefore, play a very negative role in the health and lives of the poor women of India. These injectable contraceptives are rarely, if at all, used in the advanced countries. This drug is certainly inappropriate for use in our Family Planning programme.

Dozens after dozens of such new drugs are being marketed every year but very few are really better than the earlier ones, many being out and out inferior. Between 1975 and 1984, a total of 508 new chemical entities were marketed and, according to a study, only 35 of these had “new structure/therapeutic improvement.”¹³ The moral of the story is that though scientific advances have made possible the production of better and safer drugs, the drug companies are promoting “me too” type of drugs, or even downright irrational drugs.

Irrational Drug-Combinations

As remarked in the beginning, this is a much bigger problem. Fixed dose combinations have some disadvantages and dangers because of which such combinations should be avoided as far as possible. Medical authorities have recommended only about 20 such combinations because in these 20 cases, fixed dose drug-combinations are really needed. (Please see appendix for details). The rest are all irrational combinations.

Disadvantages and Dangers of Fixed-dose Combinations

1. Unnecessary use :

A combination of a painkilling agent with a tranquilizer in a preparation leads to unnecessary use of the tranquilizer since in most of the painful conditions, it is not at all necessary to give a tranquilizer. In a particular patient, if a doctor feels that the patient really needs a tranquilizer along with the painkiller, he can give an additional tablet or can crush them together into a powder and give it to the patient. When some special initiative is needed to combine two drugs, then unnecessary combinations are much less likely to occur. If readymade combination of a painkiller with tranquilizer is available (for example : Proxymon, Subhinol/N compound, Walagesic ... etc.) the doctor is much more likely to use such a combination irrespective of whether it is really necessary or not. Such unnecessary use is widely prevalent in medical practice today, thanks to the high-pressure salesmanship by drug companies and the apathy and ignorance of a large number of doctors. The Government has banned this combination, but the companies are still selling it!

Unnecessary use of any drug means increased chances of allergic reactions or other side effects and unnecessary increased cost to the patient; and hence must be avoided.

2. Increased hazards :

Any unnecessary drug combination generally carries increased risk of allergic manifestations and side effects. But certain drug combinations are particularly hazardous either to the individual patient and/or to the society at large and hence need special mention.

(a) *Fixed Dose combination of Steroid* with an anti-inflammatory agent or an antiasthmatic agent; or an antifungal skin ointment ... etc. In all such cases, steroids are being used much more than what is really necessary. Bronchial asthma and Rheumatoid arthritis are such disorders which tend to recur and hence have to be treated for years and perhaps lifelong. A fixed-dose-preparation containing a Steroid leads to unnecessary use of Steroids not only once but repeatedly. Addition of Steroid leads to

temporary dramatic relief and the patient demands from the doctor "that particular drug" which gave him a dramatic relief. Many times a patient goes directly to the chemist, shows him the old pack or bottle or receipt or prescription or even just tells him the brand-name and takes this Steroid containing drug on his own for prompt relief. Use of Steroids are fraught with many serious dangers and since the F.D. Combination leads to unnecessary and repeated use of this drug, the patient is unnecessarily exposed to the risks of repeated, long-term use of Steroids. Moreover, the Asthmatic or Rheumatic patient develops a kind of dependence on Steroids and for such patients a regular treatment with increasing doses of Steroids becomes a necessity. This not only exposes the patient to Steroid-toxicity but in addition, his doctor is left with no powerful medicine when the patient lands into a very severe and resistant attack of Bronchial asthma (Status Asthmaticus). This patient may die in such an attack since in such cases, steroid is the life-saving drug; but has been rendered ineffective in this case because of repeated prior use.

One more disadvantage of any fixed dose combination is that the dose of each ingredient cannot be adjusted according to the need of the individual patient since a change in the dose leads automatically to a change in the intake of all the ingredients of that preparation. This disadvantage is particularly troublesome in case of Steroids, since their dosage requirements show a great deal of variation from one case to another.

In fungal skin infections, or other conditions, a fixed dose combination of steroid with an antifungal or antibacterial agent in the skin ointment may lead to temporary dramatic relief, but it also changes the local appearance of the affected skin and in cases of lack of cure, a review of diagnosis becomes difficult because the characteristic features of the skin lesion are altered by the application of a Steroid. Besides, Steroids reduce local resistance and the infection may flare up. Such flaring of infection becomes particularly dangerous in eye-conditions.

In view of the dangerous fixed-dose-combinations of Steroids, there was a demand to ban such Fixed-dose combinations. The Health Ministry in a Gazette Notification of 23rd July, 1983, banning 22 categories of harmful/irrational combinations, had included the following category also: "F. D. Combination of steroids for internal use except combination of steroid with other drugs for the treatment of Asthma." In our view this exception is objectionable for reasons already explained above. Similarly exclusion of ointments for external use is also wrong. The drug companies continued to sell F. D. combinations of steroids even after this order was passed. Apparently the law in India does not apply to the powerful interests.

(b) *Fixed Dose Combination of Chloramphenicol with other drugs*: Medical textbooks say that Chloramphenicol should be reserved for the treatment of typhoid fever and some other life threatening conditions only. F. D.

combination of Chloramphenicol with other drugs (Streptomycin for example) leads to its use in other conditions. Haphazard use of Chloramphenicol leads to emergence of bacterial resistance not only to diarrhoea-causing-bacteria, but the resistance is transferred through "R-factor" to typhoid-causing bacteria also. Thus we are losing an extremely potent, cheap drug of choice for Typhoid fever due to its F. D. combination with other drugs.

Chloramphenicol can cause life-threatening aplastic anaemia and its unnecessary use on account of its F. D. combinations is condemnable.

The drug Consultative Committee had recommended in 1980, a ban on all F-D-Combinations of Chloramphenicol. But the ban order of 23rd July 83, has curiously, and unjustifiably exempted its F-D-Combination with Streptomycin. It is precisely this combination with Streptomycin which is its most frequently used, most irrational and dangerous combination!!

(c) *Penicillin-Streptomycin combination*: Medical textbooks say that Streptomycin should be reserved for treatment of Tuberculosis and a few other specific, selective indications as given by standard Medical text books. A Strepto-pen combination means a person who harbours tubercle bacilli may get this combination for say five days for say an infected wound and would now harbour Streptomycin-resistant TB germs. (After five doses of Streptomycin, the tubercle-bacilli would develop resistance to Streptomycin due to inadequate dose and duration of treatment with Streptomycin.)

3. At the Cost of Essential Drugs:

One of the important consequences of irrational drug-combinations is that limited and hence very valuable resources are spent on these irrational drugs leaving very little money, and other resources for essential drugs. This is true both at individual and social level.

At individual level, if due to unnecessary F. D. combinations, the drug bill increases, the patient would buy only a few of the prescribed medicines and the essential medicine may be bought in much less quantity than what is prescribed, or occasionally not at all. At national level, according to one estimate, out of Rs. 1200 crores of drugs sold in India in 1980-81, only about Rs. 350 crores of drugs were rational drugs, the rest being unnecessary, irrational drugs and drug-combinations.¹⁴ The majority of such irrational drug-combinations consisted of so-called tonics, cough mixtures, irrational painkillers etc. A more definitive information is available on the wastage involved in the production of these categories of drugs.

A study of 47 top-selling *antidiarrhoeal preparations*, as listed in the CIMS, was done by Dr. Shishir Modak, a renowned paediatrician from Pune, for the Medico Friend Circle. In his scientific scrutiny based on the latest authentic scientific information, he found that only 7 out of these 47

preparations could be scientifically justified. The rest were irrational drug-combinations in some way or the other, twenty of these 47 were of such nature, that according to this paediatrician, they should be banned; the rest twenty could be improved and used.¹⁵ In a similar study conducted by Dr. Jamie Uhrig and Dr. Penny Dawson, it was found that out of 59 top-selling brands of analgesics and antipyretics, (painkilling and fever reducing drugs) only 14 were scientifically justified; 18 needed to be banned immediately on account of harmful ingredients. Earlier, Dr. Kamala Jaya Rao, then the Deputy Director of National Institute of Nutrition, Hyderabad had studied a few randomly selected top-selling multivitamin preparations and found that none of them conformed to any scientific formula.¹⁶ Similarly in an analysis of commercial cough mixtures, it was found that none of the cough-formulae were scientific. Many cough-formulae contained an "expectorant", (an agent supposed to bring out the sputum) and at the same time a drug meant to suppress the cough-reflex! To be sure, this is the height of irrationality!! In another study, all the over-the-counter-drugs randomly selected for the study were found to be unscientific in their formulations.¹⁷

These studies give an indication in a concrete way, about the extent of wastage involved in drug production in our country in the form of irrational drug-combinations. Shortage of essential drugs is the other consequence of the production of irrational drug-combinations since scarce resources of a backward country are being squandered away. We have shortage of such essential drugs like : vitamin A, Iodized salt, Chloroquin, Inj. Streptomycin, measles, polio, triple, BCG vaccines. Besides the shortages in drug production in absolute terms, what is more widespread is non-availability of essential drugs, due to poor purchasing power of the patient, or the poor budgetary allocation to the Government health-centres and hospitals, and in addition, squandering of the limited budget on the purchase of irrational drugs.

Stop the Production of Irrational Drugs

Both the aspects of the tragic situation (abundance of irrational drugs, shortage of essential drugs) created by the profit-hungry drug industry are interlocked. Hence, if essential drugs are to be made available to the needy, the production of irrational drugs and irrational drug-combinations must be stopped. To achieve this aim, a *Drug Review Committee* should be appointed which would make a list of all the drugs and their combinations not recommended by standard textbooks but currently available in the market. All the drugs in this list should be banned. If tiny, backward Bangladesh could ban so many irrational drugs, why cannot India do so? Only an increased public pressure would compel the Government to take this long overdue policy decision.

Rational Drug Combinations

Combining two or more rational drugs is advantageous in case of some very few, selected drugs and sometimes is even necessary. Let us briefly see the scientific rationale of such selected few drug-combinations and their particular examples.

1. *Synergism* : Two drugs are said to have synergism when they facilitate each other's pharmacological action and hence their total effect is greater when given together compared to the sum of their independent actions. For example : Sulfamethoxazole + trimethoprim — the great invention in the field of antimicrobials; thiazide diuretic with ganglion-blocking antihypertensive agent; Benzoic acid + salicylic acid (for treatment of superficial fungal infection of the skin); Levodopa + Carbidopa (for treatment of Parkinsonism); Oestrogen + progesterone in oral contraceptive pills; glucose + sodium chloride in Oral Rehydration Solution.

2. *Enhanced Efficacy* : This is also a kind of synergism, but there is either no linking of each other's pharmaco-chemical actions or such a linkage is still not clear. For example : Aspirin + Codeine; Isonex + thiacetazone/ P. A. S./Rifampicin/ Ethambutal (to reduce the emergence of drug-resistance to Isonex in the treatment of Tuberculosis); Calcium with Vitamin D (for better absorption); Ferrous Sulfate + Folic acid — (Haemoglobin levels would not rise above a 11 gms% by Iron alone if there is simultaneous Folic acid deficiency and is not simultaneously met)

3. *Combined nature of the problem* : Vitamin 'B complex', multivitamin, Ferrous sulfate + Folic acid, Vit A + Vit D. Vitamin B deficiency is generally that of all the components of Vitamin 'B complex'. Many times there is simultaneous deficiency of all the Vitamins in famine conditions, in generalized undernourishment and hence a multivitamin preparation is justified in such cases. Deficiency of Iron and Folic acid, and sometimes of Vit A and Vit D coexists since their dietary sources are similar, hence their respective F. D. combinations are justified.

4. *Reduction of side effects or toxicity* : Isonex + Vitamin B6 (Vitamin B6 prevents Peripheral Neuritis caused by prolonged use of Isonex); Ephedrine + Phenobarbitone — as antiasthmatic (Phenobarbitone counters the central nervous system stimulation caused by Ephedrine); Phenobarbitone + Phenytoin Sodium as anticonvulsant (reduction of dose of both individual

drugs due to combination and hence reduction of their toxicity); Magnesium hydroxide + Aluminium hydroxide as antacid (the latter tends to cause constipation; the former is a laxative).

There could be a few more rational F. D. combinations. But the simple, general rule is that a F. D. combination is justified only when there is a loss in the therapeutic advantage in not combining the two drugs. All other drug-combinations are irrational and should not be allowed.

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Unscientific Therapeutics and Drug Policy

(Dr.) T. Sunderaman*

Introduction

The absence of any comprehensive drug policy and the existence of a policy that encourages extensive price decontrol, liberal licencing and free access of multinationals gives free play to 'market forces'. This leads not only to an economic drain of crores of rupees and to economic and technological subjugation, but also to the erosion of the practice of scientific medicine. While both the Doctor and the patient continue to view drugs at an individual level, as some sort of magic bullet, an antidote for every ill, international Finance Capital has quietly subverted its role to an enormous degree and has turned the production and sale of drugs into the Twentieth Century's second most profitable industry — second only to armaments.

That the world's most profitable industry, armaments, led to the birth of the military-industrial complex and the resulting threat to world peace and the deliberate provocation of wars is well known. Today it is not out of place to talk of a similar situation in the field of Health — so great is the growth of the Health industry which includes not only drugs but diagnostics, insurance and hospitals. Yet few realize the threat to Health that such a development poses.

Unlike all other commodities in the market, in the case of drugs, the consumer has no say over the choice of the commodity he purchases. He goes entirely by the Doctor's prescription. The Doctor should ideally be deciding by the patient's health requirements and cost considerations alone. But in practice, few, if any, doctors have any idea of cost of the various drugs and brand names. Medical education in India is also such that a medical student's therapeutics is divorced from actual clinical practice. Thus when he qualifies as a Doctor the actual drugs he prescribes are those he picked up from medical representatives and his seniors. Subsequently, in the absence of any system of continuing medical education programmes, almost all his information about drugs comes from the medical representatives.

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Besides, in India, unlike in the US or UK, no unbiased independent drug information is available to Doctors. The prescribers' journals existing are industry controlled. Even a conscientious Doctor is forced to rely on the Drug Company's material.

The pressures and indeed the whole attitude generated by the industry leads, on one hand, to over-prescription of all drugs, and on the other, to prescription of inessential, irrational and downright hazardous drugs. The availability of an increasing number of such drugs as OTC drugs (over the counter drugs) has led to a dangerous increase in the consumption of drugs.

Estimates of inessential or harmful drugs in the market vary from 75 to 90 per cent, the percentage being much higher in the Third World countries. In UK one out of five of the 4500 preparations listed in the British National Formulary, and in USA eight out of twenty-five of the most frequently prescribed drugs in 1976, were considered of questionable value. In India the estimated number of brand names in the market vary from 40,000 to 60,000 — one of the largest in the world. The estimated percentage of inessential drugs among these is about 90 per cent. The problem is further compounded by the sobering knowledge that one in five drugs in the market is substandard if not downright spurious.

This 'pill for every ill' approach to Health has pushed to the background all the other facets of Health care. The need to explain to a patient about his problem, the inquiry and advice regarding diet, living and working conditions, the probing for stress factors and other contributory factors in the environment, and the very important ability to own up to the limitations of the medical profession and medical science have all been swept away by this culture.

Extent of Unscientific Medicines in the Indian Market

To form an idea of the magnitude of the problem faced in India I will briefly review the extent of the Indian problem using the criteria applied in Bangladesh under the provision of the Bangladesh Drug Ordinance of 12 June 1982.

To give concrete examples of the situation today, I have chosen the December 1985 issue of MIMS (Monthly Index of Medical Specialities). This along with CIMS are the most commonly used reference books by practitioners. But I must stress that the study represents only the tip of the iceberg. MIMS lists only 1630 brand names out of an estimated 40,000 brand names available in India. The most obnoxious drugs are largely, though not entirely, eliminated. Only the most popular and frequently prescribed drugs are retained. For example out of 46 available combinations of Chloramphenicol and Streptomycin in the market, MIMS lists only 6;

only 19 Analgin containing drugs compared to 162 in the market; and only 3 liquid preparation of Tetracycline as compared to 16 in the market.

This paper confines itself to the MIMS issue only because of our inability to analyze the complete list of drugs. Hence the figures I present should be multiplied by a large multiplier to sense the real extent of the problem.

In the following pages, the different points of the 'Bangladesh Drug Ordinance' are quoted along with illustrations of the existing situation in the Indian Market.

1. "Prohibition on (a) Antibiotics in combination with other Antibiotics, Corticosteroids or other active substances and (b) liquid paediatric formulations of Antibiotics harmful to children (e.g., Tetracycline)".³

There are 97 such unacceptable preparations listed in MIMS though only 13 are in the section on 'Antibiotics'. The rest come in 'eye and ear drops' and 'anti-diarrhoeals'.

By far the worst offenders are those in the section on antidiarrhoeals. Diarrhoea is the most common disease in this country and it is the biggest killer in the Third World. Most diarrhoeas are self-limiting, i.e., they are cured by themselves — only oral rehydration being needed for support. Most are viral that do not respond to antibiotics. But obviously the drug industry will not allow such a big market to go by. Every conceivable combination has been tried.

Chloramphenicol and Streptomycin combination is one such example. Chloramphenicol is a dangerous drug meant for use only in Typhoid and related infections and perhaps in very serious infections like Meningitis. Streptomycin must be restricted for use only in Tuberculosis to prevent the emergence of Streptomycin resistant Tuberculous strains. Yet MIMS lists five of these drugs. Further it lists 10 other formulations containing Streptomycin in combination with other drugs.

Then again drugs that interfere with bowel movement must not be combined with antibiotics in fixed-dose combinations especially for children as they are not to be used in infective diarrhoeas. We find this rule flouted by as many as 10 entries. Pectin and Kaolin combinations are 16.

Now that ORT has received due publicity, the drug companies have moved into this field also. They add special flavours, special packing or some useless additional minerals and sell these packets under brand names at exorbitant prices.

Tetracycline syrups were banned in India by a gazette notification in 23rd July 1982. Yet Pfizer's Terramycin syrup and two Doxycycline syrups (doxycycline is a long acting Tetracycline) are mentioned in the latest issue of MIMS.

Then there are curious combinations like Sandocycline which combines Tetracycline with two obscure drugs, Broxyquinoline and Brobenzoxaldine. Indication mentioned is gastrointestinal diseases!

In eye and ear drops, the combination of Corticosteroids and Antibiotics are liberally used — 23 for eye and 15 for ear. Of Course MIMS mentions that 'Steroids are not to be used in fungal, viral and Tuberculous infections, infections not controlled by appropriate chemotherapy and in Glaucoma' which would cover a majority of cases. But the immense potential for misuse is obvious.

It is to be noted that all the examples mentioned above are of not just inessential, but of hazardous drugs.

2. "Prohibition on combinations of analgesics (there is no therapeutic advantage, it only increases toxicity especially in the case of kidney damage). Prohibition also on combinations of analgesics with iron, alcohol or vitamins".³

Out of 59 analgesic preparations listed in MIMS, only 14 are rational. One must remember that most of these formulations are sold over the counter and the gross overuse of this category of drugs is compounded by the irrationality of the formulations. Often drugs are added in totally inadequate doses e.g., in fixed drug combinations containing analgesics combined with vitamins or sedatives. Drugs like Analgin which are banned abroad are dumped in our country on an enormous scale — 162 products with Analgin are available in the market. Not only has Analgin been proved to cause Agranulocytosis (a fatal disease), but much cheaper, more or at least equally efficacious, and much safer substitutes like Aspirin and Paracetamol are available.

3. "The use of Codeine in any combination form is not allowed as it causes addiction".³

MIMS lists 13 such drugs. Ironically no single drug preparation of Codeine is listed.

4. "Combinations of all types are prohibited with some exceptions that include some eye, skin, respiratory and haemorrhoidal preparations, Co-trimoxazole, oral rehydration salt, anti-malarials, Iron-Folic acid combinations and certain B-complex vitamins".³

A vast majority of drugs listed in MIMS would fall under this category. There are also numerous examples of drugs where all the constituents are useless, but together they make even less sense — especially in cough mixtures which are dealt with later.

A typical example of such irrational combinations is Pasuma 'Strong' by Merck, which is a combination of Methyltestosterone, a hormone with serious side effects if used without care, Recephedrine which is contraindicated in many subgroups of patients like hypertensives, Vit 'E' and Caffeine which have no therapeutic value. The combination is recommended

by MIMS for functional impotence, which translated for the layman means impotence due to psychiatric/emotional causes and male hypogonadism. In practice, Merck promotes this drug for any male with any sexual problem. An overwhelming majority of such are due to psychiatric causes. Giving hormones and ephedrine, which has a psychostimulant (euphoric) side effect as a placebo, is criminal. Yet Pasuma 'Strong' is one of Merck's most profitable products.

5. There is a prohibition on Vitamins in combination with other Vitamins or any other ingredient (e.g. minerals). An exception is made for B-complex Vitamins, other than Vit. B₁₂. Vit. B₁₂ is acceptable only as a single ingredient injectable product. Liquid Vitamin formulations are prohibited, except when supplied for babies in small bottles (upto 15 ml) with a dropper. Other liquid Vitamins are prohibited because of wastage of financial resources and the tremendous misuse involved'.³

There is a medical reason for this stricture on Vitamin B₁₂. Vitamin B₁₂ dietary deficiency is very rare as its daily requirement is very low — in the order of a few micrograms. However, when due to malabsorption or other rare causes, B₁₂ deficiency does occur, its detection will be hampered by giving other vitamins or subtherapeutic doses of Vit. B₁₂, which will lead to a crippling neurological disorder. MIMS lists 163 drugs containing Vitamins in its October 1985 issue of which not a single one is a single drug product!

6. 'No cough mixtures, throat lozenges, gripe water, alkalis, etc., will be allowed to be manufactured or imported as these are of little or no therapeutic value and amount to great wastage of our meagre resources'.³

MIMS lists 70 such preparations. Some of the most ridiculous combinations and unheard of chemicals are used in these. Take for example Merind's VITMOL compound. Its constituents read as follows : Malt extract 1.870 gm, Wild cherry fluid ext. 0.5 ml, Glycyrrhiza fluid extract 0.25 ml, Guaiacol 63 mg, Pot. creosote sulfonate 0.22 gm, Calcium hypophosphate 0.1 mg, Potassium hypophosphate 50 mg, Sodium hypophosphate 50 mg, Ferric hypophosphate 6.25 mg, Strychnine (which is specifically banned in India in tonics) 0.26 mg, and alcohol 9% v/v 1.3 ml per 15 ml. The only compound in this mixture which may have some value is alcohol! There are many other compounds with 20 or more constituent chemicals.

7. 'The sale of tonics, enzyme preparations and restoratives is prohibited with the exception of Pancreatin and Lactase (which are permitted as single ingredient preparations). Such products have no therapeutic value and are sometimes habit-forming'.³

Listed under tonics in MIMS, are 45 preparations, under enzyme preparations are 32 preparations, and under mineral and nutritional additives are 54 preparations (mostly useless). Scattered under various headings like Vitamins, Anabolic Steroids, food products etc., are many more such useless products that we could well do without.

8. 'Some drugs are being manufactured with only a slight difference in composition from another product but having similar action. This only confuses both patients and doctors. This will not be allowed.'³

The Indian market is full of such products.

9. 'This provision generally restricts products of marginal or uncertain therapeutic value and also harmful products subject to misuse.'³

Under this heading come the Anabolic Steroids. The only disease where there is definite indication for their use is Aplastic Anaemia. Even here, there is a lot of controversy and current opinion is against using Anabolic Steroids. Ironically, Aplastic Anaemia is most commonly caused by drug abuse. In practice Anabolic Steroids are almost always misused, and being dangerous drugs known to cause a wide variety of side effects including Hepatic Carcinoma, they clearly ought to be restricted. Another example is Vit.E which has no known therapeutic value. 26 products are listed. Now the market is being flooded with new generations of drugs for Ischemic heart disease, like Clinium, Dilazep, Iladmin, etc. Similarly, drugs like Xipamid, Indipamide and Metoprolol are second generation costlier drugs which have equal or less effect than established drugs.

10. 'This provision prohibits the sale of prescription preparations which are not included in current editions of either the British Pharmacopia or the British Pharmaceutical codes.'³

11. 'Certain drugs, in spite of known serious side effects and possibility of misuse, having favourable risk-benefit ratio, may be allowed to be produced in limited quantity for restricted use. These will be prescribed by specialists only.'³

This provision though difficult to implement points to the problems with certain drugs like Gentamycin. There is no denying that Gentamycin is a valuable drug, especially against organisms like *Pseudomonas*. Yet it is liberally used by practitioners for trivial infections like diarrhoea, often as a first line drug, leading to a number of renal complications and drug resistant strain of *Pseudomonas*.

12. to 16. — These criteria are economic criteria.

12. 'Drugs may not be imported into Bangladesh if adequate quantities of identical or similar drugs are produced in the country.'³

13. 'Basically the same provision (as 12.) applies to the import of raw materials for pharmaceutical products.'³

14. 'The role of the multinationals in providing medicines for this country is acknowledged with appreciation. In view of the calibre of machinery and technical know-how which lies in their hands for producing important and innovative drugs for the country, the task of producing antacids and Vitamins will lie solely with National companies, leaving the multinationals free to concentrate their efforts and resources on those items not so easily produced by smaller National companies. Multinationals will, however, be allowed to produce injectable Vitamins as single ingredient products.'³

15. 'No foreign brands will be allowed to be manufactured under licence in any factory in Bangladesh if the same or similar products are available/ manufactured in Bangladesh as this leads to unnecessary high prices and payment of royalties. In the light of this policy, all existing licensing agreements should be revised.'³

16. 'No multinational company without their own factory in Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on a toll basis.'³

Controls on Non-Allopathic Drugs

In India, we urgently need to add one more criterion. This relates to Ayurvedic drugs. As the common man's knowledge of the abuse and cost of Allopathic drugs increases, one reaction is to turn to indigenous medicine. Thus, commenting editorially on the drug policy the *Hindu* concludes: "more important perhaps than sharing of tasks between MNCs and the indigenous drug industry is the fillip needed for Indian system of traditional medicines like Ayurveda, Unani and Siddha whose claims to greater cost-effectiveness in the health delivery system especially in rural areas cannot be brushed aside easily"⁵. Unfortunately, it is not so simple. Though essentially born of empirical study, native medical systems have yet to shake off the feudal shackles that have obscured its scientific content. At such a time the same commercialisation that has disrupted science in medical therapeutics is taking over in the field of indigenous medicines. Most drug companies including multinationals have jumped into the lucrative Ayurvedic market. LIV-52 sales are in the top ten. Ranbaxy manufactures Garlic, and Duphar manufactures Ginseng. Combination of Ayurvedic and Allopathic drugs are flooding the market. Thus, Stadmed's Tonoliver has 15 Ayurvedic and 5 Allopathic constituents. Being Ayurvedic they escape all quality control. No scientific evidence of efficacy is needed and none are provided. And as the market picks up, so too do the prices. It

is too naive to expect Ayurveda to provide the goods where Allopathy has failed, for it is not the failure of Allopathy but the subversion of science by industry. The need to impose quality controls and proof of efficacy and price controls and to prevent unscientific integration of Ayurvedic and Allopathic medicines is an urgent legislative task.

Need to Educate the Medical Profession

Surprisingly the medical profession is largely unaware of the issues involved in the Pharmaceutical Industry. Doctors need to be systematically educated about these issues. Unfortunately, WHO's action programme on Essential Drugs has a budgetary allocation of under five million dollars a year — less than would normally be spent on promotion of one successful new drug. This is just to highlight the immense amount of effort necessary to counter the propaganda machinery of drug companies.

The advantages of each essential drug, for a given indication, over all the others available in the market has to be spelt out. Detailed material about its use and superiority has to be highlighted within the profession even while we point out the reasons for deletion of the rest. Lopsided emphasis only on the irrational drugs would, in itself, be unscientific. Though it is not in the scope of this paper, it needs to be emphasised that about 250 drugs are indispensable for Health care. Paradoxically many of these essential drugs are unavailable or in short supply. The essential drug list and its rationale must be made a compulsory part of the medical curriculum.

The medical profession gains monetarily from the drug-dependency of the population. The tonics, vitamins, restoratives and injections that the public demands are an artificially created demand in which the medical profession cannot be excused. Generic prescription will reduce the mysticism that surrounds a doctor's "prescription" and while it will mean better Health, it will also mean a more "accountable doctor". Clearly, sections of the medical community will always remain opposed to these reforms for reasons that have nothing to do with the oath of Hippocrates.

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Inessential and Useless Drugs in the Market

(Dr.) V. Brahma Reddy*

Introduction

In this paper I shall limit myself to one of the important aspects of the drug industry, namely the useless and harmful effects of some drugs.

This paper is a result of our own experience from "free check up camps" conducted by us for the public in villages, High Schools and Colleges. Each such camp was followed by a "Health Education Class". As a part of the class we discussed the role of drugs and the drug industry also. The response was overwhelmingly positive.

Here I present some of the examples we took up in our classes. The list is naturally not exhaustive as there exist thousands of formulations in the market.

Protein Powders and Liquids

In our country where 60 per cent of the people survive below the poverty line, the main aetiological factor for disease is poverty, due to which people are deprived of a proper and nutritious diet. So protein calorie malnutrition tops the list as the contributing factor to ill-health. Drug companies have entered this area in a big way and claim that they are preparing protein powders and liquids to suit the present necessities. Following is a study of some such products :

Table - 1

Preparation	Amount of Proteins	Cost (L. T. extra)
Proteinules	90 grams in	Rs. 27.83
(Alembic)	225 grams tin	
Promolon	90 grams in	Rs. 18.54
(Sarabhai)	225 grams tin	
Trophox	100 grams in	Rs. 41.44
(Raptakos)	250 grams tin	

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Protone liquid (Aristo)	13 grams in 200 ml	Rs. 16.70
Proup liquid (NATCO)	13 grams in 200 ml	Rs. 17.00
Hipro liquid (American Remedies)	13 grams in 200 ml	Rs. 19.90
Alprovit (Alkem)	13 gms in 200 ml	Rs. 17.60

An adult needs (wt 60 kg) 60 grams of protein a day. A child (10 kg) needs 3 — 4 grams of protein per kg body weight a day. Thus a child weighing 10 kg. needs 30 grams of protein a day. If he has to be given adequate amount of protein from Proteinules (a 225 grams tin lasting for 3 days), his per day treatment would cost Rs. 10/-. Further, if he is given Protone liquid he has to consume more than two bottles a day at cost of Rs. 35/- a day.

Here an alternate formula is described (called Hyderabad formula, taken from SPM text book by J.E Park) :

Table - 2

Ingredient	Amount	Approx. cost
Wheat	400 grams	Rs. 2.00
Bengal Gram	160 grams	Re. 1.00
Groundnut	100 grams	Re. 0.80
Jaggery	200 grams	Re. 1.00
Total	860 grams	Rs. 4.80

Contains 113 gram of Protein.

Thus a child suffering from protein calorie malnutrition, if given this formula needs to spend Rs. 1.25 per day as against Rs. 10/- for a proprietary protein powder or Rs. 35/- for a protein liquid. This Hyderabad Powder contains a comparable amount of calories, vitamins and minerals, annulling the argument of the drug companies that their preparations contain vitamins etc. But this proposed powder does not carry with it an attractive packing, nor is it promoted by aggressive sales techniques. But these factors do not contribute to the treatment of PCM.

Glucose Powder (Glucon-D)

Glaxo company charges Rs. 9.50 for 200 grams of a glucose packet. Thus a kg of glucose costs Rs. 47.50. It is prescribed, or purchased by patients over the counter, for weakness, fevers, Infective Hepatitis etc.

For non specific disorders like malaise, fever etc., glucose has no role to play. In Infective Hepatitis, the mainstay of treatment is rest and large quantities of Carbohydrates. Carbohydrate equivalent to 1000 cal. can be given by way of 250 grams of sugar, which costs not more than Rs. 1.25. If we want to give the same in the form of glucose it costs Rs. 12.00.

"Glaxo" claims that they are giving a nutrient in the form of glucose which is absorbed in just 15 minutes. But sugar is digested in just the same time. It is broken down into glucose and fructose and absorbed. When our bodies can prepare glucose from sugar, why should we spend Rs. 11 extra to inflate the profits of Glaxo company? Moreover, if our digestive system is incapable of breaking down sugar into its constituents, it is almost certain that the body has also lost the capacity to survive.

Vitamin B₁, B₆, B₁₂ Preparations (injectables — the 'red injections')

As many as 126 drug companies are in market with their 'red injections'. In a typical injection of this kind the composition is :

Table - 3

Constituent	Amount	Actual daily requirement
Vit B ₁	100 mg	1-1.2 mg
Vit B ₆	100 mg	1 mg
Vit B ₁₂	1000 mcg	2-3 mcg

Patients who complain of weakness, body ache, tingling numbness in extremities and a multitude of other complaints are prescribed such injections. Brand names of such formulations include Nuerobion (E. Merck), Macraberin (Glaxo) etc., costing around Rs. 2.50 per ampoule.

If such an injection is given, out of 100 mg of B₁ only 1-1.2 mg; out of 100 mg of B₆ only 1 mg; and out of 1000 mcg of B₁₂ only 2-3 mcg will be used by the body and the rest is excreted in the urine.

Pure deficiency of B₁₂ causes Pernicious Anaemia, and subacute combined degeneration of the spinal cord. The condition is so rare that many professors of medicine have not come across even one such case. Here some references are worth quoting :

"Even in vegetarians — symptoms of B deficiency appear after periods varying from 2 — 20 years" (Beaton G. H. et al (1976) in *Nutrition in Preventive Medicine*, W.H.O., Geneva).

"At present, there is little evidence that Vitamin B₁₂ deficiency anaemia represents an important Public Health problem" (Layrisse M et al (1976) in *Nutrition in Preventive Medicine*, W.H.O., Geneva).

Vitamin E Preparation

It is marketed as "Evion" by E. Merck at 100 units per capsule, costing Re. 0.35 each.

Vit. E deficiency has been reported to be associated with habitual abortion, testicular degeneration, muscular dystrophy and myocardial degeneration in animals. There is no evidence of any deleterious effects caused by Vit. E deficiency in man. It is evident that the anxiety of infertile couples is being encashed by the drug company.

Placentrex (Albert-David)

It is an aqueous extract of healthy human placenta containing Alkaline Phosphotase.

It is claimed to be useful in tissue regeneration, Pelvic Inflammation, Primary and Secondary Sterility, Indolent Ulcers, Atrophic Rhinitis, Bronchial Asthma, Tuberculosis and a dozen or so other diseases. Each ampoule costs Rs. 2.50. However, no text book of medicine or pharamacology mentions that Placentrex is useful.

Yet it is one of the most widely prescribed injections all over the country.

Memory Mircales

These are the drugs that are claimed to be useful in cases of memory loss, mental retardation, mood disorders, depression, unsociability, etc. Some such preparations are :

(a) **Encephabol** (E. Merck)

Each 100 mg tablet costs Rs. 2.00

(b) **Hydergive** (Sandoz)

Each 1 mg tablet costs Rs. 4.00.

The therapy comprises of 3 – 6 tablets daily for several weeks. There is no reliable evidence from any authority which shows that these drugs are useful. Most Doctors know that there is no drug that can regenerate lost neurons or alter the genetic cause of mental retardation. Yet they continue to be widely prescribed.

Styptics

These are drugs that are claimed to be useful in stopping haemorrhages. Some such preparations are :

Styptobion (E. Merck)

2 ml amp. costs Rs. 4.65

Styptochrome (Dolphin)

2 ml amp. costs Rs. 2.00

Styptindon (Indo. Pharma)

2 ml amp. costs Rs. 2.00

Botrapase (Juggat Pharma)

1 ml amp. costs Rs. 14.00

Following are the important causes of haemorrhage and the recommended line of treatment :

- Bleeding from cuts and wounds* : In minor cases bleeding stops on its own due to the mechanism of clotting and local vasospasm. In cases of massive haemorrhage, pressure bandage and surgery may be necessary.
- Bleeding due to bleeding diathesis* : Bleeding is continuous until the deficient factor is replenished.
- Massive Haematemesis* : Usually occurs due to ruptured oesophageal varices or upper gastro-intestinal tract Ulcers. Replacement of lost blood and other specific measures such as surgery etc., are the measures required.
- Massive haemoptysis* : viz. due to Pulmonary Tuberculosis. Needs treatment of Tuberculosis and replacement of lost blood, if necessary.

Thus there is no role of treatment by Styptics in any of these cases. Yet they are widely prescribed by Doctors.

Pain Killers

Given below is a list of ingredients in some commonly prescribed pain killers :

Table - 4

	Aspirin	Phenacetin	Caffeine	Codeine	Rate
Aspirin	350 mg	—	—	—	0.03 ps
Aspro	350 mg	—	20 mg	—	0.08 ps
Codopyrin	350 mg	250 mg	—	8 mg	0.14 ps
Micropyrin with C	350 mg	—	—	—	0.14 ps
Capramin	250 mg	160 mg	30 mg	—	0.20 ps
Veganin	250 mg	—	32 mg	7 mg	0.24 ps

Aspirin is still the cheapest pain killer available and is highly effective. Combining it with other drugs does not make the formulation superior to plain Aspirin. Codeine is a habit forming drug due to which its use is restricted in many countries outside India.

Caffeine is a central nervous system stimulant, and in the dosage given above is useless.

Phenacetin is a nephrotoxic drug (toxic to kidneys) and it has been banned in many countries like UK, US, etc. All the above useless and/or harmful drugs find their place in combination with aspirin not to enhance the pain killing effect of the drug but to increase the price of these drugs.

Conclusion

These are but a few examples. There are a host of preparations branded as tonics, cough syrups, B-Complex syrups, growth promoters, digestants, health foods, stimulants, liver tonics, impotence erasers, etc., that run into thousands. It is a well known fact that these drugs are non-essential, useless and sometimes harmful.

While thousands of such useless formulations are available in our country, only 20 per cent of the people have access to Modern Medicine. The mainstay of treatment for most of the diseases in our country lies in providing the people with adequate food, shelter, water, Hygienic conditions of living, etc., and not in multiplying the number of formulations available.

Popular Attitudinal Changes to Minor Ailments Over Forty Years

(Dr.) P. K. R. Warrior*

The points made in this paper are not based on any scientific study, but on a general observation of trends in the small, highly literate, State of Kerala. Changes in agrarian relations, improved communications, expansion of scientific education — particularly medical education, easy access to medical facilities which were not there forty years ago, have all contributed to a profound change in the common man's attitude to minor ailments.

Following is a list of minor ailments of *short duration* :

1. A common cold — rhinorrhoea and sneezing
2. A heaviness of the head — sinus catarh
3. Early morning headache
4. All the above with malaise
5. All the above with a little fever — influenza, viral fever associated with body ache
6. All the above with a little loss of appetite
The above symptoms constitute the spectrum of what may be considered as hay fever — seasonal in occurrence.
7. Some sore throat
8. Dry cough
9. Cough productive of mucoid sputum
10. A little heaviness in the stomach
11. A few loose motions
12. Billious vomiting once or twice

The vast majority of these conditions are self limiting. No therapy is required.

The common man just three decades ago used to take these in his stride, whether poor or middle class, whether rural or urban. A couple of days' or

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at the most a week's rest, some restrictions in diet, a little fomentation with perhaps a drop or two of an inexpensive aromatic added to it and he was back to socially productive labour.

The more affluent, sophisticated and therefore fussy, considered a medical consultation necessary. And what did the Doctor do? He looked into the throat and nose, took the temperature and pulse, tapped and listened to the chest and then prescribed a mixture and perhaps a few tablets of Aspirin. He liked it because it was his bread and butter. But he would often confide to a friend, "With that the whole disease will be set right in a week. Without all that, it may take all of seven days".

What does the white collar worker, the industrial worker, the peasant and even the agricultural worker do today?

He tracks to the nearest government institution, private hospital or practitioner. He waits for hours to be seen by the medical man.

What does the medical man do? He has a crowd to be seen. He knows that these minor ailments do not merit detailed examination, diagnosis and rational treatment. Therefore, in two or three minutes, he makes a cursory examination and writes out a prescription.

This prescription is vastly different from the inexpensive mixtures of old.

It usually contains an antibiotic in case a secondary bacterial infection were to supervene on a viral infection, though the Doctor knows that antibiotics do not act on viruses.

The anti-biotic might in the long run ruin the beneficial effects of the normal intestinal flora. Therefore a hefty dose of B-complex vitamins is added. Alternatively he might prescribe a broad spectrum antibiotic which combines vitamins.

Then there is an antipyretic and an analgesic.

There might be decongestant to relieve the stuffy nose.

The whole list costs a tidy sum and eats into the family budget.

He might get cured in a week, the same period in which he used to get well without drugs 30 years ago. Or, he might continue to have Stomatitis and Gastro intestinal disturbances because of the antibiotic load and might get more Vitamin B-complex prescribed.

This change in attitude to minor ailments might be in part due to change in scientific temper. But more than that, it is brought about by a steady, motivated propaganda carried on by the drug monopolists.

One is not propagating that a cold, cough, headache or stomach upset should be overlooked. They may be harbingers of Tuberculosis, Lung Cancer, Intra Cranial Tumour or Gastro-intestinal Malignancy. It is true that there could be a one in ten thousand chance of a common ailment having sinister connotation. But can a Doctor within two or three minutes diagnose the really serious cases? Does every minor illness merit a very

detailed examination and sophisticated investigations for us to pick up early Cancer? Have we got the time, manpower, establishments and resources to do this?

Therefore, our propaganda to facilitate early cancer detection, to minimise the risk of Tuberculosis dissemination etc., has in fact thrown a whole population into the hands of greedy drug monopolists. Unknowingly we have been abetting a colossal plunder.

The unfortunate Cancer patient still escapes detection, until late, thanks to the stampede in front of citadels of curative medicine. He then falls a prey to the manufacturers of expensive anti-cancer drugs, reducing himself and his family to penury.

Haven't we better cry a halt to the spread of scientific half truths?

Haven't we better educate the people that the vast majority of common ailments are self limiting and do not need the ministrations of a medical man?

If we do this, we would have at least in part, broken the stranglehold of drug monopolists on the Health of our people.

Production and Price Controls The Achilles Heel of National Drug Policy

Dinesh Abrol & Amitava Guha***

Appropriate production and price controls are necessary in drug and pharmaceutical industry to ensure at low prices supplies of safe, essential and quality drugs. Market is an extremely poor mechanism for regulation of production and prices of drugs for the developing countries. If we wish to ensure supplies of safe, essential and quality drugs at low prices in consonance with the health needs of the people, particularly those required for preventive and primary health care, production and price controls are indispensable instruments for the drug policy. This is particularly true for the situation in developing countries because the socio-economic structures are typically such that the poor people who require essential drugs cannot afford a very large drug budget and have to be supplied essential drugs at the lowest prices possible. Production controls are essential also because, relatively speaking, the category of essential drugs is much less amenable to high pressure promotion tactics of the companies. Market signals tend to distort very heavily the pattern of local drug production in favour of inessentials.

Needless to say, the government policy on production and price controls is an important determinant of the production and price decisions taken by the firms. What these decisions will be depend very much on what this government policy actually is. Whether the policy has taken into account all the special features of this industry/market or has ignored them, is the main subject matter of discussion in this paper. To discuss the impact of drug policy as being currently practised by the government, we shall start with a very brief discussion on relevant special features relating to the structure and conduct of Indian drug industry. Then, we go on to discuss what could really be a desirable approach for the government to adopt towards the production and price controls for the Indian drug industry for the coming decade.

Oligopolistic foreign firms controlled drug industry is incapable of self-regulation

The features which are specially relevant for our discussion on the production and price controls for the Indian drug industry are (1) that the drug industry has all the problems which an oligopolistic industry dominated by a few private firms can have and (2) that it has all the characteristic problems which an industry dominated by the foreign companies can exhibit.

In 1983, the Indian industry consisted of about 9000 licensed drug manufacturers. Of these, large scale units numbered 250 and small scale units 8750. The total investment estimated in 1983 in the industry was about Rs. 650 crores. Of which one third is estimated to be in the public sector units which account for about ten per cent (10%) of the total formulation market and about sixteen to seventeen per cent (16 or 17%) of bulk drug output reported in the country in 1983-84.

In the public sector, we have the big units of Hindustan Antibiotics Limited, Indian Drugs and Pharmaceuticals Limited and three small production Units which were Private units and have been taken over only recently by the government after they went sick.

The organized private sector comprises about 200 units. After the introduction of FERA 1973, there are now only 8 units in drug industry in the foreign sector. Speaking from the point of view of control of managerial drives of private firms, the most important consideration in design of the production and price controls required for the strict regulation of drug industry, ex-FERA units are still, in our view, essentially foreign-controlled firms. With 10 per cent foreign equity, the Units get characterized in other countries as foreign-controlled firms. (See table 1.) In India, even with 40 per cent equity, the units are getting the treatment equivalent to the Indian units which in our view is an anomaly that should be removed immediately. In the companies which have brought the equity down to 40 per cent, the pattern of foreign control has not changed even marginally. Dilution in favour of thousands of Indian share holders has actually enabled these companies to expand their control over the Indian economy. The Hathi Committee had made a clear recommendation on this issue that the equity should be parted either in favour of financial institutions or public sector units which we think could have alone ensured dilution of foreign control. Since this recommendation has not been implemented, even the units which have brought their foreign equity down to 40 per cent should be considered only as foreign units for all purposes. See table 2 taken from the Hathi Committee report for the industry, structure and ownership pattern, which gives a much more authentic picture of managerial control existing in the drug industry.

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For the sector-wise value of production of bulk drugs and formulations during the period 1974-75 to 1984-85, see table 3 which gives separately the production figures reported by the Ministry in 1985 for bulk drugs and formulations for the public, Indian private and foreign sectors in the drug industry. One can see that after 1976-77 separate figures for different sectors are not available.

For discussion on the oligopolistic nature of industry, we present below details of concentration existing today in the Indian drug industry. If we take disease/application specific submarkets as the basis for the study of degree of concentration, it is clear that the Indian drug industry seems to satisfy almost all the conditions of an oligopolistic industry. An oligopolistic industry is said to be one which is dominated by (a) few producers, (b) whose product mix is narrow, (c) which turns out more or less homogeneous products, differentiated by their usual means of products differentiation, and (d) where the degree of interdependence among producers is quite high. From a very recent study done by Dr. S. Singh on this issue, we see that while in general there exists a high degree of concentration within almost all the segments (See table 4) but even in those market segments where the number of firms producing similar competitive multi-purpose products is quite large one cannot really conclude that the market of these segments is competitive because drug producers often in these segments differentiate their products and promote them through the high pressure sales tactics using the advantages of the brand names and trade marks.

This high degree of concentration exhibited by the drug industry has several implications. A direct implication of the high degree of concentration is reflected in the feature that there is hardly any effective price competition in this industry. From the small scale industry there is some price competition but because of their very inadequate promotional network the impact of price competition is marginal. Promotional expenditure is an important source of the market power of the drug companies. It is a well known fact that the Indian drug industry spends much more on drug promotion rather than on R & D for new drugs or processes. See table 5 for the comparative statement on expenditure on sales promotion and R & D in the Indian drug industry.

Product Differentiation Promotes Production of Irrational Drugs

Drugs producers differentiate their products by their brand names and trade marks and compete mainly through the product or promotional competition rather than price competition. Drugs are promoted primarily to doctors, who prescribe those for patients. Through various sales promotion techniques attempts are made to create the habit among doctors

of prescribing brand names. Then there are also over-the-counter (OTC) drugs which are the non-prescription drugs promoted directly to the general public. Backed by vast promotional network, the drug companies are capable of distorting the genuine marketing information and pushing the people to consume all kinds of irrational and hazardous drugs. Numerous cases of promotion of such drugs can be cited for the Indian drug industry. The industry is surviving, in a way, only on the basis of such promotional effort. Not just surviving, rather one should say that it is fattening on account of such promotion. A large majority of drug formulations currently manufactured in our country are Inessential and are not in consonance with the real health needs of our people. (See table 6).

Today, we have over 60,000 formulations in the Indian market. Many formulations are said even to be irrational and hazardous formulations which should be weeded out. Such a large number of formulations, in our view, has only one explanation that each of the 9000 formulators has a brand of its own, and indulges in product differentiation to compete in the market. Many drugs in the market are, therefore, irrational combination drugs, a direct consequence of the means which the companies employ to remain competitive. WHO Essential Drug List contains only 7 fixed dose ratio combination drugs out of its list of 250 essential drugs. Needless to say, irrational combination drugs increase cost for the consumers and they pose other serious problems like increased chances of drug interaction, makes monitoring of adverse drug reactions difficult, makes drug control and quality control more difficult, etc. Irrational and hazardous drugs is not a subject of our paper. The only point we will like to make here in regard to large number of formulations is that as long as the industry is free to produce what it likes, it is almost impossible that the people will get rational drugs. They will continue to get much more of trash only. Drugs amenable to high pressure sales promotion techniques can be, by definition, almost excluded from the list of essential drugs. Thus, if the product or promotional differentiation as a means of competition is actually responsible for the production of irrationals and increased burden on the consumers, then it is obvious that the industry should be subjected to strict production controls. *In our view the first production control required to be implemented in India, is that the drug industry will have to go completely generic. The drugs should be marketed only in the generic names. This is also the recommendation of WHO. It is also the recommendation made by the Non-Aligned countries Conference which formulated this actually to be one of the most urgent requirements of rational drug policy to be implemented in any developing country.*

Without Regulation Industry will Produce Inessentials

Not only irrationals, this industry is famous for producing in large

quantities all kinds of inessentials like tonics and vitamins, health drinks and other inessential drugs like digestive enzymes, alkali mixtures, restoratives, cough expectorants, gripe waters, sex stimulants, etc. Even before the 1978 policy the production pattern was no different. See Hathi Committee Report. See table 7 for today's situation which gives top sellings of 1984 for Indian drug industry and table 8 which gives for four major companies in this country their production of non-essential drugs as a percentage of companies' total drug production. The lesson is clear that over-production of inessentials cannot be stopped if the industry is left unregulated. Essentials like anti-TB drugs, anti-malarials, anti-leprotic drugs are bound to be in shortage because the private industry cannot promote these drugs in an irrational manner.

There are examples of irrational promotion in the case of essentials also, like the promotion of costly Ethambutol and Rifampicin as the first drugs of choice over PAS and Dapsone, which are cheaper and affordable alternatives. Patient compliance can go down in all those cases where long term treatment is involved if the costly treatment is promoted as the first line anti-TB treatment. Examples can be multiplied. For the decline in the production of first line treatment drugs see table 9 which gives an example of irrational decline of anti-TB drugs of first choice produced by Pfizer. *Therefore, it is a matter of great urgency for the consumers that the government implements strictly the production controls which will include first of all the strict implementation at least of licensing controls which were introduced in 1978 policy. It is our considered view that there is absolutely no evidence to the effect that the Indian drug industry which is dominated mainly by the private firms would produce all the essential drugs we really need, if it is left to be guided by the invisible hand of market.*

Withdraw Immediately Delicensing from the Drugs Industry

In a mixed economy like ours, the licensing controls have been introduced with promotional as well as regulatory objectives. In the Indian drug industry, for example, the licensing controls have had the following as the key objectives : (i) the regulation of capacities, so that the anarchy prevailing in an Industry which is dominated by the private companies remains within limits and, (ii) the proper control of entry of different types of units into the industry i.e. sectoral reservation, so that the objectives of self-reliance, balanced growth and equity are also realized simultaneously along with the objective of essential drug production at low prices.

Licensing has a special roles to play in the drug industry. Since there does not exist any appreciable price competition and the axe falls on the promotional strategies of the firm, the licensing capacities are an important marker for this planning of production for the industry. For example, if

the regulation of capacities does not provide the correct signals it is very likely that under production of essential drug would be the resultant feature.

Delicensing, given this problem of production planning, is going to, in our view, precisely result in cases of under production of rational essential drugs. Under the scheme of delicensing (introduced for 94 drugs during last year), already many ex-FERA companies have registered massive capacities which can ensure growth of these companies for atleast the next ten years. See table 10 for the comparison of capacities registered by drug companies under the scheme of delicensing with the proposed Seventh Plan targets. Capacities 3 to 10 times the Seventh Plan target have been registered which is going to definitely aggravate the anarchy prevailing in production decisions of this industry. The scheme is likely to create a situation of no production or insufficient production in several products that have been delicensed. The entire drug planning process is going to be actually in very serious trouble because of the delicensing of this industry.

Delicensing does not mean automatic increase in the production, an impression which the name tends to create. This is very well confirmed even by the industry's last few years experience which clearly shows that from 1978 atleast 75 drugs out of the 94 delicensed drugs were open for all the sectors (except for FERA and MRTP which is any-way the case today also). Sanctioning of capacity has never been a problem in drug industry if one wanted to get a license for new capacities. Especially, in cases where massive imports are involved today, adequate capacity has existed for many of the products. But no ex-FERA, the main beneficiary of the loopholes of the 1978 drug policy implementation, took up the production. See table 11 for the pattern of production in the cases where massive drug imports are involved, only because of MNCs not making the requisite effort. They have both technology and capital to produce many of these drugs but their interest lies more in bulk drug imports and the local production of vitamins and house-remedies which are decontrolled items. See table 12 for the relative contribution of MNCs and Indian companies to different categories of drugs.

Delicensing covers drugs from all the price control categories. Delicensing can also mean that the industry will enter now, speaking relatively, with more freedom into the production of much more profitable category III and decontrolled category IV drugs. See table 13 for unauthorised production of drugs of higher profitability by multinational companies. Delicensing will actually lead to quite serious problems for many small scale sector companies which produce today substantial quantities of bulk drugs included in the delicensed category. Why only problems for the small scale sector? Even where the Indian sector companies dominate or have a substantial role, ex-FERA companies can attempt expansion which

may lead to serious undermining of the proposed objective of indigenization of the 1978 drug policy.

Therefore, it is only appropriate to ask that the scheme of delicensing should be immediately withdrawn. The companies can be asked to provide commitment that the capacities that they have registered will be worked within one year. For those who fail to give this clear commitment, the action we can suggest is that their capacities for those drugs be immediately cancelled. And for those who are giving commitment but they fail to work the registered capacities within the stipulated time, the action we propose is that there should be a strong disincentive introduced into 1978 policy, such as penalisation in regard to future sanctioning of capacities by the Government to the company so that there is really no scope for misuse of licensing controls.

Withdraw Broad-Banding Because it is Counter-Productive Measure for Drug Industry

Broadbanding (reported in the national press as one of the new industrial policy measures to be implemented in the drug industry) aimed at encouraging the economies of scales in the industry will help only the proliferation of irrational formulations. This is because the measure implies permitting the companies to make by themselves any minor changes in multi-ingredient formulations they like without the change of active ingredient. Already there are too many fixed dose irrational combinations in the market which require elimination. This measure will actually aggravate the problem. Broadbanding cannot imply even any significant economies of scales in the drug industry as in most cases each product has its own technology and needs independent infrastructure and raw material.

Broadbanding would also lead to more of drug disinformation, already a serious problem in this industry. Already weak quality control would get even further weakened. Price regulation of this industry can also become more difficult because mark-ups will be even more difficult to calculate as the proliferation of drugs in the market will take place in a big way with the proposed new measure of broadbanding. Profit ceilings will have to be used as the key price control measure. The measure of profit ceiling is extremely difficult to enforce, given the fact the industry is dominated by a small number of foreign-controlled companies which are capable of working through infra-firm transactions. *Thus, it is our considered view that atleast for the drug industry, broadbanding should be used only for one purpose, that is broadband licensing for only dosage forms for the formulation sectors.*

Implement Essential Drug Ratio Parameters

There should be actually no concession in the drug industry on the fixed ratio

parameter of essential drug production by each company, atleast the figure of 20 per cent which was introduced in the 1978 drug policy should be implemented. Rather we now feel that the Government should now revise this control in the following manner : in addition to the control of 20 per cent bulk drug production, we stipulate that the production of essential drug formulations shall be a minimum 75 per cent of total formulation turnover of each manufacturer (to be achieved within one year of the policy announcement) and shall be brought upto 90 per cent in five years. The priority drug formulations shall constitute 60 per cent of the above essential drugs turnover of the manufacturer and shall be raised to 80 per cent the essential drug formulations in the next five years. The priority drug formulations as earlier mentioned include all the life saving drugs, drugs needed for national disease control programmes and those drugs which are needed for use in diseases having greater mortality, greater morbidity, severe sequelae and communicability. The above suggested production quotas should include all dosage forms of essential and priority drugs. Only this kind of strict production control can ensure reduction in the production of inessentials (a luxury which India can hardly afford) and provide for the production of essential drug formulations.

The rationale of the above proposed ratio parameter relating to compulsory production of essential drugs stems from the failure of the industry to self regulate itself. It is viewed often by the critics that this kind of measure will introduce an unnecessary control which will introduce rigidities of harmful consequences. They argue that actually the problem of essential drug production can be easily solved if the Government makes the production of these drugs sufficiently profitable. They have been claiming that these essential drugs do not get produced only because the Government has made the production of these drugs a highly unprofitable activity by insisting on an unreasonable pricing policy. It may here be sufficient only to point out that even before 1978 when it was hardly under any strict price controls, the industry did not care to produce these essential drugs. See table 14 as a case of persistent under utilization of capacity for seven of essential categories of drugs during the period between 1970-78. It shows that even when there was uniform mark-up (DPCO 1970) also the production of Inessentials did not really come down; rather it continued growing.

Drug Pricing and DPCO 1979

One of the most controversial issues related to the Indian drug Industry is the issue of drug prices and drug price control order promulgated in 1979. Below, we give the main features of DPCO 1979.

(a) The DPCO 1979 divided the drugs into four categories. The mark-ups

allowed for the first two categories, covering largely essential drugs of high priority, are respectively 40 per cent and 55 per cent. For the third category of drugs, separate pricing for each producer is the case with a stipulation that in no case the mark-up should exceed 100 per cent. Drugs in category IV have been left free of price control. Besides laying down mark-up limits, additional limits of 'leader prices' based on prices of selected efficient producers have been proposed which are not to be exceeded by anyone. And consequently, it suggests that if prices in category I and II drugs are found lower than the leader prices, the prices will stay frozen at the lower level and will require permission for upward revision.

- (b) In the case of bulk drugs which are manufactured indigenously or even imported, Government will fix : (i) retention prices for individual manufacturers, importers or distributors of such bulk drugs; (ii) a pooled price for the sale of such bulk drugs. If in case the prices of bulk drugs used by the manufacturer are lower than the prices allowed to him, the manufacturer should deposit the excess amount into an account named 'Drug Price Equalization Account' and also sell the formulations only at such prices as may be fixed by the government.
- (c) New drugs developed through original R & D efforts in the country and which have not been produced elsewhere are exempted from price control for a period of five years.
- (d) Maximum pre-tax return on sales, exclusive of excise duty allowed, ranges from 8 per cent to 13 per cent, depending on the nature of firms' production and its R & D activities.

The DPCO 1979 has been subjected to severe criticism from industry circles. Their main objection is to the lower mark-up of 40 per cent and 55 per cent allowed on category I and II drugs. The recent NCAER study which is financed and initiated by OPPI has for example suggested that the mark-ups in category I and II are too low and the break-even mark-up exceeds 63 per cent which is the average for drug industry, be of any size. The study argues that the sales promotion cost has greatly increased due to certain governmental regulations, insurance, interest, increased salaries, trade margin, travelling and administrative expenses.

Need of Unbiased Study on Drug Pricing

Our problem is firstly with the fact that this study has been undertaken at the instance of an interested party and thus it cannot be taken as an unbiased study of the drug pricing controversy. Therefore, we feel that before any revision in the pricing policy is done there should be an independent study to assess the cost and profitability, as well as availability and price from the point of view of consumers.

The reasons to which the NCAER study and industrial circles attribute the increase in cost can be taken care of very well, in our view, if profit-making is not made the sole basis of the drug industry. Differential drug pricing suggested by the OPCO 1979 was based on the assumption that essential drugs need much less sales promotion expenditure than the rest, and thus, the industry should be allowed a lower mark-up for category I and II. And the second assumption was that lesser profits made on category I and II drugs could be made good by the higher profits in category III and IV.

There is nothing wrong in our view in the assumptions that the DPCO 1979 actually had with regard to drug pricing. The problem is that the drug industry which is largely dominated by private companies and foreign firms is not amenable to any lax regulation. The government has not shown actually the necessary political will required for implementation of the 1978 drug policy provisions which are not acceptable to the drug industry.

The principle of reasonable profitability for the industry should be acceptable to one and all if the industry is cost conscious and is ready to fulfil its social responsibility. The view that the existing drug price control mechanism has strangled the growth of this industry is, in our view, a bogus claim raised by the industry, which has no truth at all. By any standard the Indian drug industry has been growing by leaps and bounds. A recent report in the Economic Times (ET) of March 18, 1986 provides details of the kind of gains made by the industry during the recent period. The ET report notes that the average appreciation in pharmaceutical shares since the beginning of this year was 30 per cent against the overall improvement of 15 per cent in the ET (all industries) index of share price. The report provides the examples of upward trend for all types of companies.

Hoechst share price shot up by 32.4 per cent since the turn of the year; Hindustan Ciba-Geigy share price registered an advancement of 45.6 per cent; Bayer's share price went up by 45.5 per cent; Eskayef by 33.4 per cent; Warner Hindustan by 52.3 per cent; and Ranbaxy by 47.6 per cent. Though Pharmaceutical shares registering this kind of massive gains has been a regular phenomena in India, but perceptibly the recent gains are even higher. See table 15 for the upvaluation trend in share prices since 1981. It is not at all surprising that the report attributed this upward trend to expectations that the new drug policy would enable the pharmaceutical companies to undertake massive expansion and diversification.

Who says drug companies have been incurring losses? See tables 16 and 17 which give profitability and dividend figures for different drug companies for the most recent period for which information is available.

Of course, the drug companies have not failed to counter the above stated impression brought out by their critics. They have been pointing out that these gains have been made by industry on account of other interests like pesticides, fine chemicals, toiletries, cosmetics, etc. It is difficult to check up their claims at the level they want us to do, because there are no break-up figures available.

Drug Industry Claims are Unreasonable — Some Evidence

Thus, the alternative we are left with for the time being, is to make a study of limited publicly available information on the very cost structure of drugs and drug pricing. It is a difficult task because the data available is scanty. Indirect evidence on bonuses offered by industry and the past record of industry with respect to drug pricing are the two main indicators we shall use to evaluate the controversy on pricing issue.

Take the BICP data on 34 bulk drugs, the prices for which were declared by the manufacturers and fixed by the BICP before the promulgation of DPCO 1979. See table 18 from which it can be clearly seen that price reduction made possible by the BICP's study of the cost structure of these 34 drugs ranges anywhere from 10 per cent to 80 per cent. The average percentage reduction for all the 34 drugs works out to be 40 per cent. This table clearly highlights the fact that the companies cannot be believed for what they say. We need an independent study of the pricing issue.

Another piece of evidence regarding the companies' irresponsibility is their court cases on drug pricing. There are 22 bulk drugs of eight companies of which Glaxo, Hoechst, Cynamid and Pfizer are the major companies, all foreign companies, who have obtained stay orders on prices of bulk drugs produced by them. In addition to 22 bulk drugs, there are more than hundred formulations whose prices have not been implemented because of the stay granted by the High Court. There are 52 multi-vitamin formulations produced by Abbott, Sandoz and Pfizer, the prices of which were affected by the judgement of Bombay High Court. Other than multi-vitamins there are formulations of Warner Hindustan, Parke Davis, Fullford and many other foreign companies who have gone to the High Courts and obtained stay orders on their prices.

The price control system for all major products of foreign firms has totally collapsed in their favour on some reasoning or the other, mainly technical reasons, advanced by these companies in the court. See table 19 for the magnitude of differential in prices and extra gains these companies have made on account of higher prices charged for the concerned products.

The other evidence we wanted to present relates to bonuses offered by the drug companies with regard to Category I and II drugs where they

have been claiming that they are making losses. Terramycin, Orisul, Dependal, Ledermycin, Wysolone, Antepar, Uni Carbazan, are a few example where 4 to 15 per cent cash discount is common today in drug business.

It is quite clear from the above presented limited evidence on pricing practices of drug companies that all is not well with the argument of losses being incurred by the companies in drug business. They are hiding the truth. Their sales promotion expenditure is unduly high (13% on average). The evidence presented by us here, you would agree, clearly highlights the case for a thorough investigation into the cost structure of drugs and profitability of drug companies, on an immediate basis by an independent source.

The government can provide relief by doing away with heavy duties (30-40% is presently the additional cost on account of duties in the drug business). The trade commission shall be fixed at 20 per cent. However, it should be also stipulated that this is the total commission which will be paid from the principal manufacturer to the distributors and the intermediaries.

Wanted Pricing Policy that will Protect the Consumer and Encourage the National Sector

Below, we also give our few suggestions on the principles that the government should use in drug price fixation. In the absence of production controls, implementation of cost plus mark-up leader price based formula used presently for the drug pricing seems to have actually encouraged, in our view, only inefficient penultimate intermediate based drug production. In the early stages, liberal cost plus formula is alright when the industry is just being established. But in the long run as the industry matures, it can only be against the consumers' interest. To start with, for drugs/formulations manufactured by the multinationals which are being produced for more than seven to ten years, and produced still from the intermediate or penultimate stage, we should now review the prices and the present leaders cost plus mark-up based price fixation method should be replaced with a new system of normative cost conscious drug pricing for the said selected drugs. The industry is fairly mature to face such a measure. Consciously, new drug normative pricing formula should aim at encouraging all the relevant 1978 policy goals, like the goal of efficient drug production, promotion of national sector and protecting the drug consumer.

Differential mark-up combined with self regulation or price controls for a selected few, leaving the rest to be sold in open market in the absence of any strict production controls, can imply only one thing, that is we will

be encouraging the industry to be inefficient and make it produce more of inessentials and irrationsals.

Therefore, introduce price controls for all drugs. No drug should be left out from the span of price control. New price controls should encourage generics in the market. This is important because the MNCs in general charge higher prices compared to the National Sector for the same drug due to their higher market power. See table 20 for differences in prices of brand and generic drugs.

Canalize Raw Materials and Drugs Imports

Without the canalization of raw materials and intermediate imports, it is our view that uniform mark-up (the proposal given by OPPI) will help much more the foreign controlled companies because the MNCs are able to ignore quite effectively the mark-ups ceiling for individual profits through the mechanism of overpricing of Imports which contain an element of in-built exaggerated profits.

The special provisions regarding price decontrol of new drugs also operate in favour of the MNCs. Increased uniform mark-up of 90 per cent (as reported in national press as the new pricing formula) can mean only much more burden for the consumers who are already so over-burdened. Uniform higher mark-up for essentials will be a disaster even for many firms, like companies producing Terramycin.

Tax Relief for Essentials

Give all possible further tax relief for marketing essential drugs in the generics. And finally we again repeat that the government should make no changes in the price formula on the basis of the NCAER report recommendations, as it is a biased report produced and financed by the OPPI which represents mainly the foreign companies' interest in the Indian drug industry. Make price changes only when there is an independent report available on the costing in the drug industry.

Nationalize If Drug Companies

Do Not Implement Drug Policy Provisions

Nationalize drug companies, it is our demand, if they do not implement the suggested production and price controls. The MNCs were supposed to implement the bulk drug to formulation ratio control parameter of 1 : 5. They are refusing to implement it. See table 2, for formulations manufactured by the multinationals from imported bulk drugs. They have even started using the small-scale companies as a vehicle for swindling the consumers which should be stopped forthwith. They are permitting small-scale companies to use their brand names and trade name for producing

formulation and the marketing of the same is done by themselves. This is another method of transfer pricing and price control evasion by which also now they are evading the drug price control order 1979. See table 22. The examples are that of Phexin produced by Capsulation Services, and Zinatec produced by Biotech Pharma, both marketed by Glaxo. Hindustan Ciba, Hoechst, Roussel, May and Baker, and a number of other foreign firms are also doing the same. Stop this subversion of the government policy on the production and price controls in drug industry.

If foreign companies refuse to abide by the requisite production and price controls, it is our belief that there would be no other go but to nationalize them. Foreign controlled firms must be confined to only very high technology sector to be defined clearly by the government, leaving no vagueness on the issue. If they fail to comply with this provision provided in the policy, nationalize them. Why nationalize only the foreign firms; if the Indian private firms also fail to implement the norms and stipulations desired by the drug policy they should be nationalized.

Only the government's political will is needed. We have the technology, personnel and capital. What we need is a committed nationalist drug policy. *A drug policy which will be geared to meeting the essential drug needs at low prices as its primary goal. A policy which will promote the public sector as the leading sector. A policy which will control the prices whatever be the sector. A policy which will control the expansion of foreign firms and encourage the indian private sector. A policy which will confine foreign firms to only those areas where we have absolutely no choice. A policy which will be committed to nationalization if the firms refuse to abide by the provisions of production and price controls.*

Table 1

Name of the Country	Level of the foreign equity differentiating the foreign from domestic companies
1. Japan	10% or above
2. U. S. A.	10% or above
3. Australia	15% or above
4. France	20% or above
5. India	40% or above

Source : India Investment Centre

Table 3
SECTORWISE VALUE OF PRODUCTION OF BULK DRUGS AND FORMULATIONS DURING THE PERIOD 1974-75 TO 1984-85

Sector	74-75	75-76	76-77	77-78	78-79	79-80	80-81	81-82	82-83	83-84	84-85
BULK DRUGS											
1. Public Sector	33	43	48	47	49	59	62	67	67	61	
2. Foreign Sector	34	52	63	105*	56	53	56	72	72	65	
3. Indian Organised Private Sector	23*	25	29		75	90	95	120	121	155	
4. Small Scale Sector		10	10	12	20	24	27	30	65	74	
Total Bulk Drugs	99	130	150	164	200	226	240	289	325	355	377*
FORMULATIONS											
1. Public Sector	25	35	47	53	60	72					
2. Foreign Sector	203	300	292	697*	800*	778*					
3. Indian Organised Private Sector	172*	225*	241								
4. Small Scale Sector			120	150	190	300					
Total Formulations	400	560	700	900	1050	1150	1200*	1430*	1600*	1760*	1827*

† : Estimated

* : Component break-up not available

Source : Ministry of Petroleum and Chemicals

Table 2

INDUSTRY STRUCTURE AND THE OWNERSHIP PATTERN OF THE PHARMACEUTICAL INDUSTRY (1971-72) REGISTERED SECTOR

Particulars	Large Scale Sector		Small Scale Sector		Total	
	No.	Per cent	No.	Per cent	No.	Per cent
Full Majority* Foreign Ownership	25	21.6	9	0.39	34	1.4
Foreign Minority** Ownership	20	17.2	12	0.52	32	1.3
Indian Ownership***	69	59.5	2303	94.09	2372	97.2
Public Sector	2	1.7	—	—	2	0.1

* Full majority ownership-branches having 100% equity and partially owned subsidiaries (51%).

** Foreign minority ownership-subsidaries (49% and less).

*** Indian owned firms which have atleast some links with foreign firms are also subject to indirect control by their foreign collaborators.

Source : Ministry of Petroleum and Chemicals, Report of the Committee on Drugs and Pharmaceuticals Industry in India, 1975.

Table 4

A : MARKET STRUCTURE OF FORMULATIONS PRODUCTION

Category of Drugs	Number of Firms	Category of Drugs	Number of Firms
A. Alimentary System			
1. Anti-Antacid System	12	13. Cardio-Vascular	6
2. Anti-Diarrhoeal	10	14. Coronary Therapeutic Agents	1
3. Anti-Dysentery	5	15. Cycostatics	2
4. Anti-Spasmotics	5	16. Haemostatics	2
5. Cathartics	1	17. Peripheral Vaso. Blood Lipid Lo. Agent	1
6. Cholagogue/B/Liapy Antiseptics	1	C. Central Nervous System	
7. Enzymes		18. Analgesics	20
8. Gastro-enterology Drugs	2	19. Anti-cholingeric	4
9. Laxatives	7	20. Anti-Convulsant	2
B. Cardiovascular System		21. Anti-Depressants	2
10. Anti-Anginal	2	22. Anti-Emetics	2
11. Anti-Coagulant Solution	1	23. Anti-Epileptic	1
12. Cardio-Glycosides	1	24. Anti-Hypertensives	7
		25. Anti-Parkinson	1

Category of Drugs	Number of Firms	Category of Drugs	Number of Firms
26. Anti-Psychotic	2	65. Anti-Anaemic	1
27. Anti-Pyretic	10	66. Calliom Prep	1
28. Barbiturate capsules	1	67. Calcium Range	2
29. Cerebral Activation	1	68. Fungicides	1
30. CNS Stimulants	1	69. Hematinics	9
31. Haemorrhoidal Prep	1	70. Paediatric Drops Susp.	1
32. Neuroleptic/ Neuro-sedatives	1	71. Proteins	1
33. Psychotherapeutics	1	72. Protein Injections	1
34. Sedatives, Hyptonics	5	73. Tonics	8
35. Tranquilisers	4	74. Vitamins	16
Muscular, Skeletal Disorders		75. Vitamin injections	2
36. Muscle Relaxants	3	I. Skin	
37. Rubefacients	1	76. Acne Therapy	1
E. Hormones		77. Anti-Scabatic	1
38. Anti-Thyroids	1	78. Anti-Septic (Cream)	2
39. Corticosteroids	4	79. Anti-Tissues	3
40. Hormones & Oral prep	7	80. Dermatological prep	1
41. Oral contraceptives	3	81. Ophthalmic/Skin Lotion Prep	3
F. Genito-Urinary System		82. Anti-Diabetes	
42. Diuretics	7	83. Dextrose	1
43. Gynecic Therapeutics	2	84. Insulins	1
44. Obstetrics	1	K. Surgical	
45. Oxytocics	1	85. Anaesthetic drugs	1
46. Urinary Anti-infectives	3	86. Anti-Anaesthetics	1
G. Infections and Infestations		87. Anti-Septics	1
47. Anti-Amoebic	4	88. Anti-Rheumatics	1
48. Anti-Bacterials	2	89. Plasma Volume Substitutes	1
49. Anti-Cold	1	90. Plasma Volume Expanders	1
50. Anti-Filarials	3	91. Transfusions	1
51. Anti-Fungal	1	92. Anti-Allergic	1
52. Anti-Leprotic	2	93. Anti-Histaminics	9
53. Anti-Malarials	4	94. Steroids	4
54. Amoebicidal prep	3	M. Diagnostic	
55. Anti-Microbials	1	95. Diagnostic-Chemical	1
56. Anthelmintics	7	N. Cancer Drugs	
57. Anti-TB	7	96. Anti Cancer Drugs	1
58. Sulphas	2	O. Respiratory System	
59. Sulphonamides	1	97. Anti-carcinogens	1
60. Trichononocides	2	98. Anti-Asthmatic	7
61. Vaccines	2	99. Circulatory/Respiratory System	2
62. Antibiotics : Broad and Narrow	21	100. Cough Syrups	7
63. Antibiotics : Granules	1	101. Decongestants	5
H. Nutritions		102. Anti-Arthritics	2
64. Anabolics	1		

B : CONCENTRATION IN INDIAN DRUG INDUSTRY

No. of Products	Total No. of Producers for the drugs in (a)	No. of Firms Producing drugs in (a)
(a)	(b)	(c)
48	1	27
17	2	21
6	3	13
8	4	22
5	5	17
1	6	6
7	7	29
2	8	14
2	9	16
2	10	18
1	12	12
1	16	16
1	20	20
1	21	21

From the above table it can be seen that 21 firms (48 minus 27) in the groups of 48 drugs have monopoly hold in more than one drug and 13 firms (17 × 2 - 21) in the group of 17 drugs have dupoly hold in more than one drug.

Source : Study done by Dr. S. Singh, "Multinational Corporations and Indian Drug Industry", Criterion Publications, 1985, p. 72-81.

Table 5

R & D and Marketing by Drug MNCs

A. COMPARISON OF EXPENDITURES ON R & D AND MARKETING BY 52 MNCs

(Rupees in lakhs)						
Expenditure Head	1975-76		1976-77		1976-77	
	amount	% of turnover	Amount	% of turnover	Amount	% of turnover
1 R&D	107	0.3	136	0.4	156	0.4
2 Marketing	1317	3.8	1462	3.7	1534	3.6
Ratio of 2:1		12		11		10

Source : M. Bhagat, Aspects of Drug Industry in India. Centre for Education and Documentation, Bombay 1982.

B. MNCs' EXPENDITURE ON R&D AND OTHER AREAS*

Outlays on R&D	Approximately 0.83% of turnover
Outlays on Sales Promotion and Administrative overheads	Approximately 33.0% of turnover

- * Lovraj Kumar Committee Report on MNCs which found that this ratio was unduly high in this sector as compared to other industries.

Source: Lovraj Kumar Committee, Ministry of Petroleum & Chemicals 1978.

Table 6

Per cent share of different groups of drugs*

	Sale (crores) (Rs.)	Per cent of total market
Systematic Antibiotics	249.02	21.15
Vitamins, Tonics, Mineral Supplement Tonics	187.78	15.95
Cough & Cold preparations, Nasal decongestants etc.	55.40	4.70
Anti-parasitics	46.78	3.97
Analgesics	44.29	3.76
Antacids	38.17	3.64
Anti-inflammatory & anti-Rheumatics	53.06	4.50
Anti T.B. drugs	30.39	2.50
Enzymes	24.69	2.10
Sex hormones	23.61	2.00

- * The above figures reveal that non-essential drugs like Vitamin combinations, Tonics and Nutrients occupy second position in terms of sales. Enzymes and sex hormones sold are comparable to the sale of anti T.B. drugs.

Source: ORGMAT 85

Table 7

MOSTLY NON-ESSENTIAL & HAZARDOUS (TOP SELLINGS OF 1984)

Rank	Drug	Sales	% of MS in Rs. lakh	Product Group
2	BECOSULES	998	1.0	B. Complex
5	BARALGAN	676	0.7	Anti Spasmodic (Hazardous)
8	DEXORANGE	619	0.6	Blood Tonic
24	HEPATOGLOBIN	428	0.4	Blood Tonic
8	VICKS VAPORUB	509	2.6	Non-Drug
20	NOVALGIN	536	0.5	Pain Killer — Banned in 15 countries
12	BENADRYL	524	0.5	Cough Expectorant
24	PHENSEDYL	344	0.3	Cough Syrup
26	NEUROBIN	413	0.4	B. Complex
27	OXALGIN	412	0.4	Anti Inflammatory
29	SUGANRIL	404	0.4	do.
31	GLUCOSE-D	399	0.3	Sugar only
38	PROTINEX	366	0.3	Non-Drug
44	DIGEPLEX	314	0.3	Digestive Enzyme Syrup

Source: ORGMAT May '84

* MS = Market Share

Broad Banding will help them to produce more of these Inessentials

Table 8

Over Production of Non-Essential Drugs

Company	Total Retail Sale in lakh Rs.	Product	Sales	% of Total Retail Sale
Pfizer	40.65	Becosules	9.98	32.57
		Protinex	3.26	
Hoechst	33.16	Baralgin	6.76	36.40
		Novalgin	5.31	
Parke-Davis	18.90	Benadryl	5.24	27.72
S. G. Chemicals	17.90	Suganril	4.12	23.02
		Oxyphen + Phenyl Butazone Group		

Source: Prepared from ORGMAT May '84.

Table 9

Anti-TB Drug Production by Pfizer

Name of Drug	Licenced Capacity	Actual Production in Metric Tons			
		1980	1981	1982	1983
PAS	110	23.80	13.78	5.70	Nil
INH	80	73.77	54.00	71.57	Nil

Source : Amitava Guha, "Glimpses of the Drug Industry in India", FMRAI, 1985.

Table 10

Comparison of Capacities Registered And Seventh Plan Targets For The Seventh Plan Demand Targets of Delicensed Drugs

Name of Bulk Drugs	Number of Manufacturers applied under delicensing scheme	Capacity already licensed	Capacity registered under delicensing scheme	Total	Seventh Plan Targets
1. Aspirin	3	44/0 MT	3010 MT	7480 MT	2740 MT
2. Chloroquin	4	616 MT	288 MT	904 MT	470 MT
3. Ampicillin	8	3065 MT	527.6 MT	834.1 MT	580 MT
4. Rifampicin	9	NA	275 MT		93 MT
5. Cephalixin	10	NA	310 MT		17.5 MT
6. Methyl Dopa	5	83 MT	291 MT	374 MT	68 MT
7. Diazepam	2	24.7 MT	16 MT	40.78 MT	5 MT
8. Pyrazinamide	6	NA	159 MT		35 MT
9. Mebendazole	2	20 MT	179 MT	174 MT	53 MT
10. Dapsone	2	248 MT	50 MT	298 MT	30 MT
11. Amodiquin	2	125 MT	12 MT	137 MT	47 MT
12. Cephalixin	10	NA	310 MT		175 MT
13. Ibuprofen	12	200 MT	383 MT	633 MT	140 MT

Source : Compilation from Government Reports.

Table 11

BULK DRUGS OPEN FOR LICENSING

	Unit	NS	1974	Imports	NS	1982-83	Imports
			MNCs			MNCs	
1. Vitamin B ₂	MT	3.00	—	30.00	21.00	—	17.29
2. Aspirin	MT	801.00	—	—	1326.35	—	74.29
3. Ethambutol	MT	NA	NA	NA	97.23	—	14.55
4. Caffiene	MT	23.00	—	—	16.05	—	74.56
5. Methyl-Dopa	MT	—	—	5.00	3.37	—	10.55
6. Salbutamol	KG	—	—	—	383.00	—	927.00
7. Chloramphenicol	MT	8	51	79	98	25	4
8. Sulphamethoxazole	MT	31	—	19	165	17	2
9. Sulphadiazine	MT	34	38	—	2.5	47	56.7
10. Chloroquin	MT	1.5	18	91.5	46	34	198.2
11. Xanthinol							
12. Nicotinate	MT	—	—	0.03	0.07	0.3	0.3
13. D.D.S. (Dapsone)	MT	—	4	1	7.5	3.4	34.5
14. Rifampicin	MT	—	—	1.2	—	—	36.9
15. Vitamin B ₆	MT	—	—	27	—	—	57
16. Panthenols	MT	—	—	14	—	—	62.1
17. Dextropropoxyphene	MT	—	—	NA	—	—	8.30
18. Thiabendazole	MT	—	—	NA	—	—	12.6
19. Tetramisole	MT	—	—	NA	—	—	6.2
20. Dexamethasone	KG	—	—	—	6.25	152.39	437.32
21. Vitamin A	MMU	—	46	—	—	.53	20MT
22. Ephedrine	MT	—	9	22	—	2	44408MU
23. Rutin	MT	—	—	—	—	—	—

Source : Government of India Reports, Ministry of Petroleum and Chemicals.

Non-Utilisation of Capacities Registered under DGTD After Dilution of Shares by TNCs

Company	Year	Number of Registrations	Utilisation of Registrations
Duphar Interfran	1980-81	39	18
	1984	8	Nil
Boeliringer Knoll	1980-81	6	3
	1981-82	4	Nil
	1983-84	4	4
Reckitt & Colman	1980-81	1	1
	1982-83	6	Nil
	1984	4	Nil
Parke Davis	1983-84	8	Nil

Source : Compilation from News Letters of India Investment Centre.

Table 12
COMPARATIVE POSITION OF CONTRIBUTION OF MULTINATIONAL COMPANIES (FERA & EX-FERA) AND
NATIONAL COMPANIES IN ANTIBIOTICS, AMOEBOCIDES, ANTI-T.B., ANTI-MALARIAL, ETC.
AND IN VITAMINS & SIMPLE REMEDIES

	TOP 20 COMPANIES			(Rs. IN CRORES)			TOP 85 COMPANIES		
	Total (20)	MNCs (11)	National (9)	Total (50)	MNCs (29)	National (21)	Total (85)	MNCs (40)	National (45)
1. TOTAL TURNOVER	589.4	329.1	260.3	1008.7	573.2	435.5	1196.3	632.1	564.2
2. TOTAL TURNOVER OF ANTI- BIOTICS, AMOEBOCIDES ETC.	204.7	73.0	131.7	327.8	128.8	199.0	390.6	139.7	250.9
Break-Up :									
Antibiotics	149.6	46.6	103.0	225.4	81.1	144.3	256.5	82.9	173.6
		(31.1%)	(68.9%)		(36.0%)	(64.0%)		(32.3%)	(67.7%)
Anti-T.B.	11.0	2.0	9.0	20.6	4.0	16.6	29.2	4.0	25.2
		(18.2%)	(81.8%)		(19.4%)	(80.6%)		(13.7%)	(86.3%)
Amoebicides	8.6	5.0	3.6	16.7	5.8	10.9	22.1	8.1	14.0
		(58.1%)	(41.9%)		(34.7%)	(65.3%)		(36.7%)	(63.3%)
Sera-Vaccines	0.5	0.5	—	1.5	0.5	1.0	1.5	0.5	1.0
		(100.0%)			(33.3%)	(66.7%)		(33.3%)	(66.7%)
Anti-Malarial	3.1	2.0	1.1	3.3	2.0	1.3	8.5	4.1	4.4
		(64.5%)	(35.5%)		(60.6%)	(39.4%)		(48.2%)	(51.8%)
Cardio Vascular	17.0	5.8	11.2	28.4	15.1	13.3	38.1	18.5	19.6
		(34.1%)	(65.9%)		(53.2%)	(46.8%)		(48.6%)	(51.4%)
Anti-Infectives	7.4	4.1	3.3	21.5	10.8	10.7	24.3	12.2	12.1
		(55.4%)	(44.6%)		(50.2%)	(49.8%)		(50.2%)	(49.8%)
Anti-Diabetic	7.5	7.0	0.5	10.4	9.4	1.0	10.4	9.4	1.0
		(93.3%)	(6.7%)		(90.4%)	(9.6%)		(90.4%)	(9.6%)
									— Continued
3. TOTAL TURNOVER OF VITAMINS & SIMPLE REMEDIES	155.1	112.8	42.3	276.2	195.1	81.1	310.1	209.4	100.7
		(72.8%)	(27.2%)		(70.7%)	(29.3%)		(67.5%)	(32.5%)
Break-Up :									
Vitamins	40.3	32.3	8.0	91.2	76.1	15.1	98.0	78.8	19.2
		(80.1%)	(19.9%)		(83.4%)	(16.6%)		(80.4%)	(19.6%)
Tonics	21.0	12.9	8.1	27.2	16.9	10.3	32.0	20.1	11.9
		(61.4%)	(38.6%)		(62.1%)	(37.9%)		(62.8%)	(37.2%)
Cough & Cold Preparations	35.2	27.9	7.3	48.7	37.5	11.2	55.7	41.4	14.3
		(79.2%)	(20.8%)		(77.0%)	(23.0%)		(74.3%)	(25.7%)
Antacids, Antiflatulents, etc.	15.9	13.1	2.8	30.0	19.2	10.8	37.8	21.8	16.0
		(82.3%)	(17.7%)		(64.0%)	(36.0%)		(57.7%)	(42.3%)
Anti Anaemic Preparations	15.2	6.7	8.5	42.0	18.5	23.5	45.5	18.8	26.7
		(44.1%)	(55.9%)		(44.1%)	(55.9%)		(41.3%)	(58.7%)
Rubs & Balms	5.6	5.6	—	12.3	12.3	—	12.5	12.3	0.2
		(100.0%)			(100.0%)			(98.4%)	(1.6%)
Protein Supplements	9.4	6.1	3.3	11.8	6.4	5.4	13.9	6.8	7.1
		(65.0%)	(35.0%)		(54.2%)	(45.8%)		(48.9%)	(51.1%)
Infant Formula	7.8	3.5	4.3	8.3	3.5	4.8	9.7	4.7	5.0
		(44.9%)	(55.1%)		(42.2%)	(57.8%)		(48.5%)	(51.5%)
Other Nutrients	4.7	4.7	—	4.7	4.7	—	5.0	4.7	0.3
		(100.0%)			(100.0%)			(94.0%)	(6.0%)

Source : ORG, April 85 to March 86.

Table 13

UNAUTHORISED PRODUCTION BY MULTINATIONAL COMPANIES

<i>Name of Company</i>	<i>Item</i>
1. Abbot Labs	Surbex T Liquid Penthothal Sodium Inj.
2. Astra-IDL Ltd.	Linctus Codeine Co Iteol Mynatal Vitoferin Vermitel Water for Injection Logascid Mucosol Morphine Hcl Morphine with Atropine Pethidine Mynatal Tabs/Caps Logascid Tabs Cellubril Caps Tibamycin Caps Leprostat
3. Glaxo Labs Ltd.	Analgesic Entacyl Erg Compound Ferrous Sulphate Livogen Crystapen V 65 mg Crystapen V 125 mg Crystapen V 250 mg Macrablin 50 mg Ancolan Multivite Forte Multimineral Pelonin 250 mg Remids Viteolin 100 mg Ostocalcium B12 with C Multivite F.M. Prepalin Forte Aminophylline Livogen (Incl. Vet.)
4. Warner Hindustan	Agarol M Emulsion Waterbury's Femibon Isokin 650 Theravita M Rediplex Liquid Tedrai C Tablets Tedrai E Tablets Sfliplex C Tablets Isokin 300 Tablets

	Nutriful Liquid Rediplex Tablets Analgesic Hc Ointment Tedrai Liquid Halls Menthio-Lyptus Koskin Linctus Isokin T Forte 100 mg Isokin Liquid Oxyour Liquid Gelusil MPS Tablets Gelusil MPS Liquid Isokin Tablets 100 mg
5. Wyeth Labs Ltd.	Wymesone Tabs Wymesone Inj. 2 ml Wycort Neomycin Oint 0.5% 5 gm/15 mg
6. Geoffrey Manners & Co. Ltd.	Ultragin Tabs Synalgesic Tabs Ultragin Elixir Synalgesic Elixir Ultragin Inj.
7. Merck Sharp & Dhorne	Cypreheptadine Hcl Perideca Thibendole Bolus
8. Cynamid India Ltd.	Aureomycin 2% Powder Aureomycin Scourt Oblets
9. Roche Products Ltd.	Ferro-Redaxon Cap.
10. Hoechst Pharmaceuticals Ltd.	Neoviassept restinon IV 10 ml Restinon 20 ml Becorox Inj. consisting of Vit. etc.
11. Pfizer Limited	Multivitaplex Drops Multivitaplex Elixir Becosule Syrup Beconex Tablets Multivitaplex Forte Capsules Dumasules Capsule Becosule Capsules Vermax Liquid Worker 100 m, 500 ml & 45 lit. Corex Cough Syrup 50 ml, 100 ml. TAO Syrup 30 ml TAO Pad. Drops 5 ml Visine Oph. Solution 10 ml Finocin Tablets Deltacortril Tablets Deltacortril Forte Tablets Deltacortril IM/IV Injection 3 ml Vials Nebasulf Eye Ointment 3 gm Nebasulf Skin Ointment 3 gm, 15 gm Nebasulf Instillation 10 ml Nebasulf Powder 10 gm Nebacortril Eye Ointment 3 gm Nebacortril Skin Ointment 5 gm, 15 gm

Durol 100 ml
Nephrol R. Tablets
Mestalone U. Vials
Terramycin S.F. Caps
Terramycin Intra-muscular sols
Terramycin Otic Solution
Terramycin Egg Formula
Pasonex-S
Amebiotic Cap

Source : Rajya Sabha Starred Question No. 38 dated 27 Feb 84 & No. 2002 dated 13 Aug 84.

Table 14

Capacity Utilisation of Seven Essential Categories
of Drugs : 1970 - 77

	1970	1971	1972	1973	1974	1975	1976	1977
Penicillin								
Capacity (MMU)	264.0	264.0	299.0	331.0	364.0	364.0	364.0	364.0
Utilisation	182.0	223.0	230.2	246.0	254.0	236.0	259.0	312.0
% utilisation	69	84	77	74	70	65	71	86
Streptomycin								
Capacity (Tonnes)	235.2	235.2	205.2	268.8	257.0	257.0	257.0	257.0
Utilisation	157.2	177.6	193.2	177.6	187.0	192.0	214.0	194.0
% utilisation	67	76	94	66	73	75	83	75
Sulpha Drugs								
Capacity (lakh kg)	9.8	10.2	14.0	14.0	21.0	21.0	25.9	25.9
Utilisation	7.8	10.1	12.6	12.6	9.7	10.6	12.3	11.6
% utilisation	80	99	90	90	46	50	47	45
Chloramphenicol								
Capacity (Tonnes)	68.4	68.4	68.4	70.8	109.0	109.0	128.0	128.0
Production	38.4	48.0	40.8	48.0	59.0	60.0	102.0	93.0
% utilisation	56	70	60	68	54	55	80	73
PAS & Its Salts								
Capacity (lakh kg)	3.8	5.4	7.2	7.3	7.8	7.8	11.1	11.7
Production	4.7	4.8	4.5	5.0	4.6	5.5	7.0	5.6
% utilisation	124	89	63	68	59	68	63	48
Anti-dysentery Drugs								
Capacity (Tonnes)	64.5	64.5	124.7	136.4	427.0	427.0	509.0	724.0
Production	78.0	83.6	83.6	87.6	168.0	175.0	205.0	143.0
% utilisation	121	129	67	64	39	41	40	20
Vitamin A								
Capacity (MMU)	25.0	25.0	64.2	66.6	45.0	45.0	45.0	45.0
Utilisation	37.0	42.2	49.2	48.4	46.0	29.0	42.0	48.0
% utilisation	148	169	77	73	102	64	93	107

Source : Centre for Monitoring Indian Economy (CMIE) : Production and Capacity Utilisation in 215 industries, 1970-77, pp. 57-58.

Table 15

WHO SAYS THE DRUG COMPANIES ARE INCURRING LOSSES

Company-wise Financial Data with Profitability Ratios for Selected
30 Pharmaceutical Companies

Name of Company	Financial year	Total assets	Net Sales	Gross profit	% return on total capital employed
1. Glaxo Lab	Jun 83	93.75	136.17	14.28	14.8
2. Hind Ciba Geigy	Dec 83	62.04	101.18	10.89	14.12
3. Hoechst (I)	Dec 83	49.70	80.67	9.00	28.25
4. Sandoz (I)	Dec 83	41.81	63.17	6.56	11.23
5. Alembic	Dec 83	33.08	56.26	5.99	15.64
6. Pfizer	Nov 83	37.50	52.08	5.99	15.64
7. May & Baker	Dec 83	31.29	41.30	5.98	6.67
8. Ranbaxy	Dec 83	37.53	37.06	3.83	13.58
9. Boots India	Dec 83	15.18	33.69	3.48	14.21
10. Burroughs	Aug 83	29.05	32.68	4.55	15.44
11. German Remedies	Dec 83	20.99	31.77	4.39	22.13
12. Cynamid (I)	Nov 83	17.76	27.55	4.95	15.55
13. Parke Davis	Nov 83	8.85	26.08	2.51	13.14
14. Warner Hindustan	Nov 83	8.55	25.45	2.53	15.55
15. E Merck (I)	Dec 83	18.52	23.18	2.12	19.38
16. Richardson Hind	Jun 83	10.18	23.30	3.15	20.21
17. Roche	Dec 83	15.30	22.30	4.50	28.34
18. Cipla	Oct 83	13.14	20.54	1.44	5.42
19. Unichem Lab	Sep 83	10.16	19.56	2.04	12.09
20. Abbott Lab	Nov 83	7.53	15.28	1.80	14.09
21. Searle (I)	Dec 83	10.35	13.52	0.92	12.07
22. Boehringer	Apr 83	6.53	11.35	3.26	29.40
23. Duphar-Int	Dec 83	7.01	12.49	-0.47	21.25
24. Nicholas Lab	Jun 83	9.84	11.31	1.29	12.20
25. Fulford (I)	Dec 83	5.88	9.42	0.64	22.18
26. Jayant Vitamin	Jun 83	14.81	8.81	1.08	20.44
27. Amrutanjan	Mar 83	4.25		0.50	21.59
28. J.L. Morison	Dec 83	4.92	8.52	1.01	17.93
29. Chemo Pharma	Jun 83	3.09	0.12	0.05	7.93
30. Zandu Pharma	Mar 83	4.47	4.94	0.50	16.27

Source : Chemical Weekly, March 5, 1985.

Table 16
WHO SAYS THE DRUG COMPANIES ARE INCURRING LOSSES?
Book Value and Price Share of Pharmaceuticals

Name of Company	31-12-81	31-3-82	31-12-82	31-3-83	31-12-83	31-3-84	31-12-84	12-2-86
1. Glaxo	20.50	22.00	31.00	21.50	24.00	24.25	24.25	83.00
2. Hindustan					277.50	285.00	262.50	1000.00
3. Hoechst	28.00	27.00	41.00	35.00	42.00	44.00	375.00	87.00
4. Sandoz	70.00	91.00	139.00	141.00	122.00	07.50	32.50	145.00
5. Alembic	24.00	23.50	36.50	31.00	37.25	38.50	85.00	124.00
6. Pfizer	15.00	15.75	25.00	21.50	30.00	30.50	40.00	71.00
7. M & B	19.50	26.50	37.50	36.50	49.00	44.00	30.50	155.00
8. Ranbaxy	23.00	24.00	39.00	33.00	56.00	67.00	36.50	200.00
9. Boots							46.00	190.00
10. Burroughs							58.00	82.50
11. German R.	26.50	29.50	35.50	31.00	32.75	36.75	36.00	95.00
12. Cynamid	29.00	28.00	38.00	26.00	34.40	41.00	38.50	66.00
13. Parke-Davis			29.50	23.50	30.00	33.00	29.50	110.00
14. Warner Hind	21.50	22.00	31.00	28.00	37.00	36.00	38.00	100.00
15. E. Merck		16.25	33.00	28.50	31.00	34.00	34.50	33.00
16. Richardson	24.00	22.50	39.25	38.00	64.00		19.00	
17. Roche			N.A.					
18. Cipla	145.00	145.00	140.00	145.00	180.00	167.00		
19. Unichem			61.00	22.00	24.00	27.50	27.00	53.00
20. Abbott	42.00	35.00	68.00	59.00	47.00	44.00	80.00	407.50
21. Searle	16.00	12.75	18.50	14.50	18.00	17.75	11.75	98.00
22. Boehringer								

23. Duphar	30.00	20.00	31.00	25.00	49.00	41.00	30.00	
24. Nicholits							19.50	
25. Fulford		21.75	34.00	30.00	47.00	56.00	76.50	
26. Jayant	6.50	5.00	9.00	6.25	11.50	11.50	10.00	
27. Amrutnjan	41.50	40.00	36.00	40.50	46.00	45.00		
28. J. L. Morrison	13.50	13.00	14.50	13.25	14.00	14.00	17.00	
29. Chemo-Pharma	32.00	18.00	22.50	22.50	22.50		22.50	
30. Zandu	100.00	100.00	100.00	147.50	147.50	200.00		
31. Bayer	-	-	-	-	-	-	-	680.00
32. Eskay	-	-	-	-	-	-	-	210.00
33. Ciba	-	-	-	-	-	-	-	600.00

Source : Chemical Weekly and Times of India, March 5, 1985 and Feb 12, 1986.

Table 17

Name of Company	Expenditure on import of raw materials, capital goods, others				Expenditure on remittance of dividends and others				Total outflow 1981	Original Equity	
	(Rs. lakhs)										
	1979	1980	1981		1979	1980	1981				
				Dividend	Others	Dividend	Others	Dividend	Others		
Hoechst	421.95	607.42	383.09	30.99	57.99	45.97	35.98	30.65	110.11	523.85	20.00
Roche	246.33	241.02	180.32	20.03	1.30	0.03	1.30	26.70	1.14	208.16	100.00
Bayer (I) Ltd	845.68	492.01	382.14	49.64	3.90	49.64	3.88	24.82	4.20	411.16	4.00
Ciba Geigy	18.95	590.52	410.34	67.73	28.95	54.18	28.13	54.18	6.24	470.76	2.00
Sandoz	500.01	503.98	684.70	18.11	53.12	18.00	53.20	31.50	61.90	778.10	10.00
Cynamid (I)	150.41	96.15	102.55	53.35	Nil	56.42	Nil	Nil	Nil	102.55	1.50
E Merck (I)	67.05	176.98	188.47	Nil	Nil	7.20	Nil	2.01	Nil	190.48	20.00
Glaxo Labs	189.40	268.80	209.80	120.80	Nil	126.90	Nil	139.00	Nil	348.80	1.50
(Figures for year ending 30th June)											
Merck Sharp & Dohme	109.50	147.01	76.19	Nil	Nil	Nil	9.72	Nil	Nil	76.19	180.00
Richardson Hindustan	8.00	13.00	21.00	7.00	Nil	12.00	Nil	15.00	Nil	36.00	0.20
Burroughs Wellcome & Co	228.38	162.18	244.46	15.00	Nil	22.50	Nil	22.50	Nil	266.96	5.00
Parke Davis	78.50	70.21	77.16	21.00	Nil	14.70	Nil	21.00	Nil	98.16	87.50
Johnson & Johnson (I)	82.22	66.85	75.94	11.54	Nil	11.54	Nil	12.15	Nil	88.09	20.00
Pfizer Ltd	189.56	68.73	97.16	90.75	0.97	124.74	0.85	105.48	0.78	203.42	2.00
Organon (I)	33.03	46.34	47.89	4.30	Nil	4.30	Nil	Yet	to be declared	97.54	N.A.
May & Baker	105.76	190.76	153.60	Nil	0.16	Nil	0.53	65.30	1.01	219.91	N.A.
Warner Hindustan Ltd	56.10	59.09	52.87	12.90	2.46	10.49	2.55	21.24	3.26	77.37	70.00
Whiffens (I)	Nil	Nil	Nil	0.62	1.62	0.62	1.81	1.20	1.10	2.30	10.00
Boots Co (I)	180.45	160.41	103.27	14.85	2.27	18.00	2.40	Nil	Nil	103.27	10.00
Alkali & Chemicals	225.00	205.00	208.00	17.00	27.00	18.00	6.00	29.00	22.00	259.00	35.34
Wyeth Labs	37.75	49.01	64.18	11.29	Nil	10.99	0.15	11.09	Nil	75.27	33.30
Uni-Sankyo	(78-79)	(79-80)	(80-81)	(78-79)	(79-80)	(80-81)	(78-79)	(79-80)	(80-81)		
	0.52	0.43	5.82	0.52	0.21	0.60	Nil	0.73	0.47	7.02	1.00
Eskey labs	(78-79)	(79-80)	(80-81)	(78-79)	(79-80)	(80-81)	(78-79)	(79-80)	(80-81)		
	55.65	74.67	71.14	7.97*	8.87	2.38	8.53	Nil*	Nil	71.14	N.A.
Ltd (SKF)	(78-79)	(79-80)	(80-81)	(78-79)	(79-80)	(80-81)	(78-79)	(79-80)	(80-81)		

Source : Compilation from Company Reports.

Table 18

Price of Bulk Drugs Declared by Manufacturers and Approved by BICP

Name of Drug	Unit	Company	Declared	Fixed
Frusemide	Kg	Hoechst	2913	1741
Sulphamethoxazole	Kg	Roche	1130	517
Trimethoprim	Kg	B. Wellcome	5950	2587
Absorbed diphtheria and tetanus vaccine	Lt	Glaxo	700	400
Chlorpheniramine Maleate	Kg	Searle I Ltd	1350	1133
Pheniramine Maleate	Kg	Searle I Ltd	900	809
Tricholine Citrate Solution	Kg	Franco Indian Pharma	100	42
Sodium Citrate IP, Potassium Citrate & Sodium acid Citrate	Kg	Suchen Lab	30	16
Oxy Phenbutazone	Kg	Synthochem	2500	1002
Hydro Cortisone	Gm	Phine Kemikals	19	15
Hydrocortisone Acetate	Gm	Phine Kemikals	19	16
Hydroxy progesterone Caproate USP	Gm	Phine Kemikals	10	7
Oestorone propionate IP	Gm	Phine Kemikals	10	6
Ethisterone IP	Gm	Phine Kemikals	22	4
Phenacetin	Kg	Amar Chemicals	111	65
Clofibrate	Kg	Ranbaxy	450	400
Ampicillin Anhydrous	Kg	HAL	2713	1952
Maprobamate IP	Kg	Pharmasyuth Chemicals	350	157
Oxyphenbutazone	Kg	Gauli Fine Chemicals	1200	1002
Estradiol benzoate	Gm	Phine Kemikals	115	30
Anti pyrine	Kg	Nuchem Plastics Ltd.	160	106
Sulphaphenazole	Kg	IDPL	271	184
Di-phenyl-my drantoin sodium	Kg	Synthochem	382	261
Calcium sennasoid 100% pure	Kg	Alembic	2400	1737
Terpin Hydrate IP	Kg	Bhavana Chemicals	50	32
Clofibrate 80	Kg	Pharma Indiana Lab	780	400
Menodione IP	Kg	Pharma Indiana Lab	1125	442
Menadiana Sodium Bisulphate	Kg	Pharma Indiana Lab	1575	430
Diphenhydramine Hcl BP	Kg	Vazivalli Pvt Ltd.	300	251
Phenformin Hcl BP	Kg	Vazivalli Pvt Ltd.	400	303
Metronidazole Benzoate	Kg	Unichem Labs	948	600
Metronidazole	Kg	Uniloids Ltd.	600	460
Di-iodo hydroxy quinoline	Kg	Uniloids Ltd	153	121
Iodo-Chlorohydroxyquinoline	Kg	Uniloids Ltd	172	134

Source : Lok Sabha Debate, August 1978, quoted in Dr. S. Singh, Ibid.

Table 19

**COURT CASES ON DRUG PRICES
AND THE EXTRA GAINS MADE BY DRUG COMPANIES**

Name of Company	Unit	Company price/ Units produced	Government price/ Sanctioned Units	Production Units	Extra Gains in 4 years (Rs. crores)
HOECHST					
Baralgan Ketone	Kg	24,735.38	1,810.20	12 T	27.15
Glybenclamide	Kg	9,800.00	2,458.20	3.29 T	2.42
P. M. Teracycline	Kg	4,836.00	2,562.00	4.50 T	1.02
GLAXO					
Betamethasone Diphosphate	Kg	2.2 lakh	1.26 lakh		
Betamethasone 17-Valerate	Kg	2.20 lakh	1.06 lakh	2.3 T	21.00
MSD (MERIND)					
Dexamethasone	Kg	1.95 lakh	0.55 lakh	0.54 T	4.90
PFIZER LTD					
Becosules	20s	7.96 lakh	5.58 lakh		
	Bot	without ED	without ED		
Becosules	100s	29.80 lakh	24.48 lakh		
	Bot	without ED	without ED		
Becosules Syrup	50ml	4.48 lakh	3.39 lakh		
	Bot	without ED	without ED		
Multivitaplex Forte Caps	20s	7.80 lakh	5.26 lakh		
	Bot	without ED	without ED		
Dumasules Caps	20s	7.16 lakh	4.58 lakh		
	Bot	without ED	without ED		
ABBOTT LABS					
Surbex-T Tabs	25s	9.5 lakh	6.36 lakh		100-150 crores
Surbex-T Tabs	100s	32.88 lakh	22.29 lakh		20 crores turnover
Vidaylin M Syrup	9ml	8.43 lakh	5.81 lakh		
Vidaylin Drops	15ml	5.13 lakh	3.87 lakh		

Source : Statement referred to in reply to parts (b) and (c) of Rajya Sabha Starred Question No. 84 for 8 May 1985.

Table 20

Differences in Prices of Brand & Generic Drugs

Name of Company	Brand	Price (Rs.)	Name of Generic Drug Company	Price (Rs.)
Chloroquin Phosphate : (each Tab.)				
Cipla	Ciplaquin	0.28	Acila	0.24
			Bengal Chemical	0.20
			Bengal Immunity	0.22
			IDPL	0.20
			Inga	0.18
Dexamethazone : 5 mg (each Tab.)				
Merind	Decadron	0.24	Prakash Pharma	0.08
John Wyeth	Wymesone	0.27	Bombay Drug	0.07
			Eros	0.07
			Alpha Drug	0.06
Aspirin : (10 Tab.)				
Nicholas Lab.	Micropyrin	0.79	Bombay Drug	0.36
			Stamac Product	0.41
			Lilly	0.15
			Paras Pharma	0.30
Indomethacin : (25 mg X10 Tab)				
Merind	Indocid	2.33	Alma Lab.	2.00
			Smith Stanistreet	2.10
			Glyco	1.50
			Jilichem	1.76
			Paam Pharma	1.25
Isoniazid : 100 mg (1000 Tab.)				
Pfizer	Isonex	35.48	Bombay Tab.	33.23
			Pharmakab	29.79
			Semit	29.75
			KSDP	26.40
Metronidazole : 200 mg (each Tab)				
May & Baker	Flagyl	0.28	Alma Lab.	0.23
			At Acc	0.18
			British Medical	0.23
			KSDP	0.23
Trifluoperazine : 5 mg (each Tab.)				
Eskey Lab.	Eskazine	0.44	Cyper	0.10
			Alma Lab.	0.07

Source : Pharmaceutical Codex '85

Table 21

**Formulations Manufactured by Multinationals from
Imported Bulk Drugs**

<i>Name of Company</i>	<i>No. of Formulations</i>	<i>Types of Formulations Marketed</i>
Boots	14	Cough Lozenges, Cold Tab., Antacids, Cough Syrups, etc.
Sandoz	23	Anti-spasmodic, Ergot, Pain Killers, Vitamins, Anti-emetics
Bayer	12	Phenobarbital, Psycholeptic, Sulphathio Urea, etc.
Pfizer	21	Tetracycline, Vitamins, Pencillin, Antiseptic cream
E. Merck	14	Vitamins, Hormones, Cough Syrup
Glaxo	31	Vitamins, Thyroxin, Steroids
Merind (MSD)	7	Psychotropics, Liver extracts
Wyeth Lab	3	Dexamethasone, etc
Burroughs Wellcome	20	Anti-Cancer, Antiallergics, Antispasmodics, Cough Syrup, Anti infective cream
Roche Product	14	Vitamins, Sulpha Drugs, Pain Killers L-Dopa
Ciba Geigy	24	Hypotensives, Pain Killers, Antiallergics, Anti-Spasmodic, Coramin, Nasal Decongestant, Skin Cream
Cyanamid	34	Chlortetracycline, thambutol, Vitamin, Tonics Haematinics
Eskey Lab. (SK & F)	30	Thiazide, Psychotropis Furazolidone, Anti-Dandruff Cream, Iodex
Richardson Hindustan	5	Skin Cream, Vitamins, Tonic, Cough Syrup
May & Baker	29	Anti-allergic, Psychotropic Cough Syrup, Antiseptic Cream, Phenobarbitones
Hoechst	6	Digestive Enzyme, Dermatologicals, Vitamins

Source : Ministry of Petroleum and Chemicals

Table 22

**Multinationals Marketing Products Made By
Small Scale Companies**

<i>Name of MNCs</i>	<i>Brand Marketed</i>	<i>Manufactured By</i>
GLAXO	PHEXIN (Cephalexin Caps)	CAPSULATION SERVICES, Bombay
HOECHST	ALBERCILLIN (Ampicillin Cap)	INGA SAPS. PVT. LTD., Hyderabad
HINDUSTAN CIBA-GEIGY	AUBRIL (Trimethoprim Sulphadiazine)	PHARMPAK PVT. LTD., Bombay
MAY & BAKER	FLAGYL (Benzoyl Metronida- zole Oral Suspension 60 ml)	BIODEAL LABS., Wadhwan City, Gujarat
MAY & BAKER	KETROPROFEN (Ketoprofen Cap)	ELEGAN PHARMACEUTICALS, Bombay
MAY & BAKER	ANTRIMA (Trimethoprim Sulphadiazine)	ELEGAN PHARMACEUTICALS, Bombay
ROUSSEL	CIDOMEX (Amoxicillin Cap)	OPTREX INDIA LTD., Srinagar
ROUSSEL	COMBIFLAM (Ibuprofen and Paracetamol Cap)	CAREWS PHARMA
GERMAN REMEDIES	CATAPRES (Clonidine Tabs)	KOSMOCHEM PVT. LTD., Bombay
US VITAMINS	FENTREX (Ibuprofen Cap)	AMERICAN PRODUCTS CO. LTD., Bombay
ETHNOR	PANTEL 200 (Mebendazole Tabs)	NR JET PHARMACALS LTD., Bombay.

Violations :

- IDR ACT - AS NO INDUSTRIAL LICENCE TAKEN BY SSI UNIT
- DPCO - 79 - AS NO PRICE APPROVAL REQUIRED FOR SSI UNIT
- NDP - 78 - RATIO PARAMETERS; OBLIGATION TO PRODUCE BULK DRUGS,
CAPACITY LIMITATIONS - SSI UNITS EXEMPT.
- IMPORT POLICY - NO QUANTITY CONSTRAINTS
- UNETHICAL - TIE - UPS WITH MNCs PRINCIPALS FOR SUPPLY OF BULK
DRUG AT PRE - DETERMINED PRICES.

Source : Compiled From a Market Survey done in Jan 1986.

Profitability on Drugs — A Survey

Mrinmoy Sarkar & Others*

Introduction

During the last few years, the drug industry has been persistently claiming that due to Drug Policy 1978 and Drug Price Control Order (DPCO), 1979, the profitability of the companies have been seriously affected. In support of their claims, they have not presented any authentic documents based on actual studies.

We undertook a study of the effect of DPCO, 1979, on the most popular brands of selected companies and on how far the present system of category-wise mark-up on drug formulations have affected the turnover of their most popular products. As drug companies are reluctant to provide information in respect of cost and profits on drugs, we had to study the situation in the market and draw conclusions.

Background

Based on Tariff Commission Report on actual cost study of 17 essential bulk drugs, Drug Price Control Order, 1970, was issued with a view to curb excessive profits on drugs. As a result the prices of some of these drugs were substantially reduced.

Hathi Committee studied the situation in the drug industry extensively and made a number of recommendations. Some of these recommendations were considered by the Government, and Drug Policy 1978 was introduced and adopted in the Parliament. Following Drug Policy 1978, Drug Price Control Order, 1979, was issued. DPCO, 1979, listed drugs in four categories for the purpose of price fixation. While Category-I formulations have 40% mark-up, Category-II has 55% Category-III 100% and Category-IV does not have any price control. Obviously, the attempt of the Government was to provide lesser margin in Category I & II groups of drugs while providing higher margin of profit in other categories.

* Mrinmoy Sarkar is a member of the Federation of Medical Representatives' Association of India (FMRAI).

In the Steering Committee meetings of National Drugs and Pharmaceuticals Development Council (NDPDC), the industry representatives demanded upward revision of the mark-ups to provide "reasonable" returns on their products. The Government has already informed in Parliament and in a Press Conference that a new Drug Policy would be introduced soon. Press reports indicate that the Government intends to make upward revision in the mark-ups under DPCO, 1979.

In this background we undertook this study to find out the substance in the pleas of the drug manufacturers for the revision of mark-ups.

Method Adopted for This Study

For the purpose of the study, we relied on "Pharmaceutical Guide" to ascertain the prices of various drugs. We also interviewed Medical Representatives of various companies, procured information and cross-checked this information with the chemists and druggists.

We prepared a questionnaire for the Medical Representatives of different companies, selected on a random basis. Reply to this questionnaire formed the basis of our study.

Our study has been based on the following 17 companies which is only a sample survey and the conclusion, based on the study are only indicative in nature, but forms sufficient ground for further intensive studies on this subject.

<i>Multinational</i>	<i>Indian</i>
Eskayef	Raptakos Brett
Glaxo	Unichem
Hoechst	Cipla
Parke-Davis	Fairdeal Corporation
Roussel	Dey's
Franco-Indian	
Cyanamid	
John Wyeth	
Warner Hindustan	
Ciba-Geigy	
Pfizer	
Burroughs Wellcome	

The products which were selected for the study were the most popular brands of these companies and they contribute a high percentage to the total turnover of the respective companies. We have recorded the percentage of each product-wise turnover to total sales turnover of each company.

We verified each product and the category of formulation it belonged to as per the Drug Policy 1978 and DPCO, 1979. We have recorded the price

of each product at 1972 level. 1972 was taken as the base-year as the drug prices were fixed at that time on the basis of DPCO, 1970. We have also recorded the prices of 1975 as some of the products were not introduced in 1972. We recorded prices of these products in 1980 to find out the effect of DPCO, 1979. We also recorded prices in 1984 for the purpose of comparison.

We have also calculated the percentage of increase or decrease of the prices of these products. In all 55 products were surveyed in this study. A complete data sheet of this study is attached as Appendix-I. We also collected information in respect of various bonus and incentive schemes offered by various companies recently on each of these products. The data sheet on this aspect is attached as Appendix-II.

Observations

Following are our observations, deduced from this study : The fast moving two to three, products of each company contribute a minimum of 31% and a maximum of 88% of the total sales turnover of the respective companies, the average being 53 per cent. Average contribution of each in this group of products was 19 per cent.

55 products surveyed belong to the following categories :

- Category I — 3
- Category II — 15
- Category III — 26
- Category IV — 11

Out of 55 products, the prices of 10 products decreased whereas prices of 42 products increased. Price variations of 3 products could not be ascertained as these were introduced by the respective companies after 1980.

10 products whose prices were reduced belong to the following categories :

- Category I — 1
- Category II — 3
- Category III — 6

Out of 17 Companies surveyed, we could not collect information from 2 Companies in respect of bonus and incentives offered to the chemists and druggists. Of 15 Companies, except one Company, all other Companies were offering bonus or incentives to the chemists and druggists for 33 products out of the 52 products studied.

The bonus varied from 2% to 15% of the price of the product. It is interesting to note that though Terramycin prices were reduced by 30% due to DPCO, 1979 and has a 55% mark-up, being a Category-II product,

the Company could offer 15% cash discount on Terramycin IM 10 ml. vial even during April 1986. Inference can be drawn that substantial margin is secured by the Company even in Terramycin Capsules. Another Category II drug, Orisul's prices were marginally reduced. The price of only one product in Category I was reduced. In Category III, the prices of 3 products were substantially reduced. These products are Co-trimoxazole and Cimetidine. Even though there was 30 to 34 per cent price reduction for Co-trimoxazole, in 1984, Burroughs Wellcome was offering 4 per cent cash discount and Dey's Medical was offering 1 free for every 8 packets, amounting to more than 10 per cent bonus, during 1985-86. Similarly for Cimetidine, Franco-Indian is offering a 5 per cent cash discount throughout the year.

For another product, Mayambutol of Cyanamid, the prices were reduced between 1972 to 1984 by 50 per cent. The Company is offering even in April 1986, 20 tablets free for 100 tablets purchased to the Chemists. It is important here to note that when a drug is newly introduced the price is substantially high. But gradually its price goes down. Ledermycin, in spite of being a Category II product, was being offered at a 5 per cent discount in 1984 to the chemists.

Conclusions

From this study we can draw the following conclusions : DPCO, 1979, did not affect the fast moving products of the drug Companies. The fast moving products (two to three for each Company) contribute a minimum of 35 per cent to the total sales turnover of each Company. The Companies offer incentives to the chemists on more than 50 per cent of the products studied, which indicates the extent of their profitability.

Even after substantial reduction of prices of drugs, the Companies are in a position to offer huge discounts to chemists. Even in Category II group of drugs, where 55 per cent mark-up is allowed, the Companies are in a position to offer up to 15 per cent cash discount.

Therefore, the claim of the drug manufacturers that due to DPCO, 1979, their profitability was substantially reduced and there was a need for upward revision of mark-ups is not tenable. Further, even with 55 per cent mark-ups, the Companies are in a position to offer discount to the chemists which indicates that the break even mark-up for these products is much below 55 per cent.

It is also not correct to compare the price rise of other commodities to that of medicines, which when introduced are generally highly priced. Therefore, it can be stated with conviction that there is no case which substantiate the claims of the drug industry for revisions of DPCO, 1979, and the Drug Policy, 1978.

Price Variations of Fast Moving Drugs of Selected Companies
and Their Categorisation

Name of Company	Product Name	% of Product's share to Total Turnover	Prices during 1972 1975 1980 1984	% Increase or decrease (approx)	Category Formulation
SKF (Eskayel)	Iodex	20%	2.90 3.35 3.55 5.77	+205%	IV
	Furoxone Tab		2.43 2.43 2.29 2.32	- 4%	III
	Furoxone Sus	15%	4.32 4.32 4.82 4.90	+ 14%	III
	Furacin Cream		2.50 2.50 3.06 5.77	+130%	III
	Furacin Powder	15%	- 2.63 2.72 5.67	+111%	III
	Furacin Oint		2.50 3.15 3.26 5.77	+130%	III
	Dependal	10%	- 2.80 2.90 2.91	+ 4%	I
Glaxo	Bethovate. N. Cream (15g.)	19%	10.17 0.17 10.58 10.58	+ 4%	III
	Bethesol Tab. (10 Tab)	11%	3.76 3.76 3.89 3.91	+ 6%	II
	Ostocalcium B ₁₂ (160 ml)	8%	4.15 4.15 5.55 5.42	+ 31%	III
Hoechst	Baralgan Tab. (10X10)	23%	36.00 36.00 37.18 37.77	+ 5%	II
	Novalgin Tab. (10X10)	11%	21.30 23.74 20.00 27.20	+ 32%	II
	Avil Expectoant 100 ml.	9%	- 6.36 6.46	+ 5%	III
Parke-Davis	Benadryl Expectoant 114ml.	20%	4.13 4.60 5.23 5.23	+ 26%	III
	Chloromycetin 12 Cap	15%	2.91 2.91 2.91 4.73	+ 63%	II
Roussel	Ferradol 454 gm	10%	6.54 8.15 8.61 18.61	+279%	IV
	Cortasmyl (20 tabs)	18%	4.18 4.55 4.81 4.78	+ 15%	III
	Synastat (10 Tab.)	12%	- - - 13.12	-	III
Franco Indian	Soframycin Cream (15 gm.)	26%	2.94 3.20 3.75 5.60	+ 88%	III
	Dexorange (280 ml)	41%	7.50 9.00 10.29 14.50	+ 95%	IV
	Sorbilin (100 ml)	8%	5.75 6.90 7.14 8.45	+ 46%	IV
Cynamid	Cimetidine (10 Tab)	10%	- - 19.65 11.43	- 39%	III
	Ledermycin 2 caps (300mg)	25%	3.00 3.00 3.11 3.20	+ 7%	II
	Autrin (15 Cap)	15%	4.79 4.79 4.96 4.98	+ 4%	III
	Mayambutol (10 tab)	18%	8.61 8.30 5.64 3.60	-59%	III

John Wyeth	Penidura LA-6 (5 vials)	46%	14.82 14.82 10.85 10.65	-27%	I
	Wysolone (10X10 tab.)	23%	18.83 20.00 21.53 21.88	+13%	II
	Aludrox gel (350 ml.)	19%	5.94 7.10 7.35 7.47	+31%	III
Warner Hindustan	Tedral SA (10 tab)	30%	2.03 2.03 2.23 2.27	+11%	II
	Gelasil (10 tab.)	22%	1.05 1.25 1.30 1.31	+29%	III
	Waterbury's Compound (470 ml.)	-	7.26 8.90 9.59 14.93	+101%	III
Ciba	Mexaform (50X10)	15%	82.63 82.63 89.57 89.55	+ 9%	I
	Orisul (50X10 tab.)	15%	77.77 77.77 73.75 63.18	- 5%	II
	Otrivin (10 ml.)	5%	3.13 3.13 4.75 6.88	+120%	IV
Pfizer Ltd	Terramycin (250 mg 100 cap)	20%	9.91 11.42 11.86 11.90	+ 20%	III
	Terramycin (10 ml vial) injection	16%	63.00 63.00 50.76 50.99	-19%	II
	Septan (10X10 tab)	9%	5.20 4.00 3.59 3.61	-30%	II
Beechams (20 cap.)	Acified (10X10 tab)	60%	- 103.90 95.59 68.00	-34%	III
	Antepar Elixir (30 ml)	-	18.38 18.38 19.03 19.03	+4%	II
	Antepar Granules (10 gm)	-	1.49 2.25 2.17 discontinued	-	II
Raptakos Bret	Hepatoglobine (300 ml)	18%	- - - 2.20	-	II
	Neogrodine Elixir (300ml)	13%	6.50 10.30 11.14 19.12	+196%	IV
	Unienzyme (25 tab.)	26%	5.90 7.00 7.48 17.72	+200%	IV
Unichem	E.P. forte (1ml injection)	14%	3.90 4.30 4.90 7.91	+102%	IV
	Incarbazone forte (100 tab.)	12%	3.45 3.88 4.02 5.84	+ 60%	III
	Asthalin (10 tab)	17%	46.00 46.73 48.46 49.05	+ 8%	II
Cipla	Ciplin (10 tab.)	10%	- 5.07 5.16	+ 2.5%	IV
	Ibugesic (30 tab)	7%	- 12.25 9.56 6.80	-44%	III
	Electral (80 gm)	45%	- Introduced 11.04	-	III
Fairdeal Corp	Vennymycin (Eye drop) 5ml	12%	in 82 4.03 4.18 5.67	+40%	IV
	Molzyme (45 tab.)	7%	1.75 2.21 2.21 2.43	+40%	III
	Enterostrep (12 cap)	31%	- 9.59 10.83	+14%	IV
Dey's	Enteromycetin (12 cap)	26%	4.27 4.27 4.41 5.97	+40%	II
	Kombina (10 tab)	15%	4.42 4.42 4.21 4.73	+ 8%	II
			- 9.50 6.62	-30%	III

APPENDIX - 2

<i>Name of Company</i>	<i>Product</i>	<i>Bonus & Incentive offered by Company</i>
Eskayef	Iodex	Nil
	Furoxone Tab	23+2 Free, Apr 86
	Furoxone Sus	23+2 Free, Apr 86
	Furacin Cream	15+1 Free, Mar 86
	Furacin Powder	15+1 Free, Mar 86
	Furacin Ointment	Nil
	Dependal M tab	23+2 Free
Glaxo Lab	Betnovate M Cream	Nil
	Betnosal Tab	Nil
	Osto-Calcium B ₁₂	Nil
Hoechst	Baralgin	Nil
	Novalgin	Nil
Parke-Davis	Avil Expectorant	15+1 Free, Dec 85
	Benadryl	
	Expectorant	37+3 Free Oct, 85
	Chloromycetin	Nil
Roussel	Ferradal	Nil
	Cortasmyl	Nil
	Synastat	Nil
	Soframycin Cream	15+1 Free Apr, 86
Franco-Indian	Dexorange	4% Cash Discount Apr, 86
	Sorbiline	5% Cash Discount Mar, 86
	Cimetidine	5% Through out the year
Cynamid	Ledermycin	5% Cash Discount, Jan 85
	Autrin	Nil
	Myambutol	100+20 Free, Apr 86
John Wyeth	Penidura	Nil
	Wysolone	5% Cash Discount, Feb 86
	Aludrox gol	Nil
Warner Hindustan	Tedral SA	Nil
	Gelusil	24+1 Free, Apr 86
	Waterbury's	
	Compound	8.33% Through out the year
Ciba	Mexaform	
	Orisul	Could not ascertain
	Otrivin	
Pfizer	Becosules	2% Cash Discount, Mar 86
	Terramycin Cap	Nil
	Terramycin IM	
	Injection	15% Cash Discount, Apr 86
Burroughs Wellcome	Septran	4% Cash Discount, Feb 86
	Actifed	Nil
	Antepar	7% Cash Discount, Apr 86
	Antepar Granules	

Raptakos Brett	Hepatoglobine	940+60 Free Mar 86
Unichem	Neogadine Elixir	940+60 Free Apr 86
	Unienzyme	20+1 free, Feb 86
	E.P. Forte	19+1 Free, Feb 86
	Unicarbazan Fort	20+1 Free Dec
Cipla	Asthalin	
	Ciplin	Could not ascertain
	Ibugesic	
Fairdeal Corporation	Electral	4% Cash Discount, Mar 86
	Vanmycetin drop	24+1 Free Apr 86
	Molzime	9+1 Free, Dec 85
	Enterestrep	Nil
Dey's Pharmaceuticals	Entromycetin	Nil
	Kombina	9+1 Free Dec 85

Generic Names Versus Brand Names

(Dr.) Amit Sen Gupta*

A drug has three names. The chemical name, a non-proprietary name and in most cases a brand name.

Thus the drug which is sold by the brand names Crocin or Calpol in the market has the chemical name *n*-acethy-para-amino phenol. It has the non-proprietary name of Paracetamol.

The non-proprietary name of a drug is often referred to as the generic name. This is not exactly correct, as generic names actually refer to the different groups of drugs with similar properties viz. Sulphonamides, Cephalosporins, etc. However, as non-proprietary names are generally referred to as generic names, I shall henceforth in this paper refer to them as such.

An overwhelming majority of drugs in the Indian Market are sold by their brand names. The generic names are written in small type, and are virtually impossible to read. All promotion and marketing is done on the basis of these brand names and a majority of doctors prescribe in brand names.

The controversy as to whether drugs should be marketed by their brand names or generic names has raged for years. The reasons advanced for marketing in generics, to put them briefly, are:

1. *Clarity*: Generic names give information about the class of drugs. Thus Diazepam and Nitrazepam are clearly related. But their brand names, Calmpose and Nitavit are not. There have been cases of prescribers, when one drug has failed, unwittingly changing to another drug of the same group or even to the same drug, thinking that such different names must mean totally different drugs. On this the text book of Pharmacology by D R Laurence has this to say "such occurrences are a criticism of the prescriber, but they are also a criticism of the system that allows such confusion".¹

Confusion over brand names are compounded by the fact that drug companies are so busy stressing on the brand, they almost never stress

upon the exact composition. That such confusions can be fatal is illustrated by this oft quoted story:

A dispenser received a written slip from the O. T. sister asking for 1 gm. of Procaine (which is used for anaesthesia). Thinking Procaine to be similar to another drug, Percaine, the dispenser used crystals of Percaine and labelled the solution Procaine. The patient into whom the drug was injected had seven convulsions in 15 minutes and died. This incident occurred in 1940 and was reported in the Lancet. Interestingly, in 1942 the makers of Percaine discarded the earlier trade name and started using the name Nupercaine. Ironically, the next year a woman died because now Nupercaine was mistaken for Novocaine (which is the brand name of Procaine).²

Some examples of brand names in the Indian Market which confuse are:

Amiline	—	psychotropic, anti-depressant
Amicline	—	anti-amoebic
Lasix	—	diuretic
Laxil	—	laxative
Celin	—	vitamin C
Ciplin	—	anti-infective
Corbutil	—	painkiller
Corbeta	—	anti-hypertensive
Restin	—	painkiller
Restyl	—	sleeping pill

Such examples are endless and hence the possibility of mistakes occurring, even fatal ones, are enormous.

The type of names chosen by drug companies for their drugs are also a part of their hard-sell campaign. Thus we have names like Neurophos, Neurobion, Calmpose, Serenace etc. These names try to convey the type of effects these drugs have or the conditions in which they are to be used. But as a single name can never convey full information, such names actually convey erroneous impressions.

2. *Economy*: Drug prices are bound to come down if a switch over is made to generics. Many drug companies can afford to charge artificially hiked prices for their brands, as they have been able to create a 'brand loyalty', by aggressive promotional and marketing techniques over the years. It has been said in a lighter vein that doctors are almost equally divided in two camps over the superiority of Bactrim or Septran. It is of course well known that Bactrim and Septran are brand names for the same drug Co-trimoxazole. Moreover colossal sums are spent as promotional expenditure by the Drug Companies to build 'Brand Images'. An estimated 33 per cent of total outlay is spent by MNCs as promotional expenditure

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and administrative overheads. These costs get added onto the prices of the final products.³

Some examples of how brand names often mean high prices will be illustrative.

Nalidixic acid — a drug used for urinary infections — is sold as Gramoneg by Ranbaxy, and Wintomylon by Win-Medicare. The respective prices for 1 tablet are :

Ranbaxy	—	Rs. 1.48 for Gramoneg
Win-Medicare	—	Rs. 3.15 for Wintomylon

Similarly for Mebendazole which is used to treat helminthic infection the figures are the following :

Table I⁴

Brand Name	Company	Price (in Rs. for 10 Tabs)
Idibend	IDPL	1.79
Mebendazole	Biddle Sawyer	2.13
Mebazole	Torrent	3.60
Mebex	Cipla	4.88
Besantin	Khandelwal	5.06
Emanthal	M. M. Labs.	5.29
Wormin	Cadila	5.31
Eben	Gufic	5.50

Another classic example of how brand names mean higher prices is shown by this :

Metroni Drugs Pvt. Ltd. makes Tinidazole and sells it to four companies, who in turn market it under four different names in the following manner:

Table II⁵

Brand Name	Company	Price (in Rs. for 10 Tabs)
Abdogyl	Biddle Sawyer	6.40
Amebomagma	John Wyeth	7.80
Fabizol	Unichem	8.90
Zil	Sarabhai	9.00

An even more blatant example of profiteering under the garb of Brand Names is that of Glaxo Laboratories. Glaxo markets two formulations, Betnelan and Betnesol, with exactly the same composition (Betamethasone 0.5 mg). Betnelan is priced at Rs. 2.08 for 10 Tabs. while Betnesol is priced at Rs. 3.91 for 10 Tabs.

That prices do come down if generic are introduced is illustrated by the recent case of Britain. Britain has introduced compulsory prescription in

generics for selected essential drugs by doctors attached to the National Health Scheme. This has resulted in a significant fall in drug prices in Britain. The Industry has already started hitting back at the new regulation. G. D. Searle, a Multinational Company, has threatened to get rid of most of its British Scientists. It claims that the Government is preventing it making sufficient profits, because one of its leading brands was 'black-listed' from prescriptions in the National Health Scheme.⁶

3. *Medical Education* : In the course of medical education, information about drugs is given in generics. All medical journals and textbooks stress on generic names. Yet when a young doctor starts prescribing, he has to make an immediate switch to brand names. In such a situation the only information he has available about drug names is that which is fed to him by the drug companies. Thus in many cases a doctor just does not know the composition of drugs he is prescribing. Given the amount of misinformation and disinformation spread about drugs by drug companies, such a situation often leads to disastrous consequences.

It is ironical that given such a situation, resistance to switch over from brand names to generic names often comes from doctors. The reasons are however quite simple. Having been 'indoctrinated' about brand names for so long, many doctors have lost the capacity to think in terms of generic names. Thus when a doctor wants to prescribe a tranquilizer, the name Calmpose comes readily to him, but the generic name 'Diazepam' eludes him. Further in the absence of any unbiased, reliable source of drug information, a vicious circle is created. It is a sad commentary on the members of the medical profession who take pride in calling themselves 'men of science', that ultimately their output is determined not by their study of books but by information pamphlets provided by drug companies.

4. *Elimination of Irrational Combinations* : Drug companies put forth the argument that generic names would be impossible to use when one prescribes combination drugs. But that is exactly one of the main advantages of going generic. It is well known, well documented and well supported by scientific medical literature that an overwhelming majority of combination drugs marketed in India are either irrational or both irrational and hazardous.

Generic nomenclature will go a long way in changing a ridiculous situation where 60,000 formulations flourish. It is precisely when, by going generic, a doctor realizes that Santiveni tonic contains 11 ingredients — most of them either useless or in unsuitable dosages — that he will stop prescribing it.

Bioavailability

Of all the arguments raised against generics, there is only one which has some scientific basis. That is in the question of bioavailability. Bioavailability means the exact amount of the active substance of a drug available in the body to perform its therapeutic function.

Most formulations, in addition to the active ingredients, contain binding substances and additives which may alter the bioavailability of the active substance. The argument put forth is that since these additives may differ for formulations by different companies, the bioavailability of the drug may differ.

This problem is likely to be faced in a very small number of cases, where prolonged treatment of chronic diseases are necessary like in Heart Disease, Diabetes, T.B., Hypothyroidism etc. Here, the solution lies in enforcing strict quality control measures and in developing mechanisms by which drug formulations by different companies can be standardised. It is ridiculous to ask for scrapping of a proposal which has so many obvious advantages only because some mechanism of standardisation of formulations needs to be worked out.

The case then for use of generic names should be an open and shut case. Not only so, but different bodies have for long favoured use of generics. The Hathi Committee in 1974 did so and in fact prepared a list of 13 drugs for immediate conversion to generics. The WHO has at various forums favoured use of generics. Why then do brand names continue? The reason again is simple. Drug companies, fired by their lust for profit, and given the enormous political clout they have come to acquire have so far managed to effectively sabotage all efforts to go generic.

Pakistan is often touted by drug companies as an example of the failure of generic nomenclature. It is well known that drug MNCs actively sabotaged the 'generic experiment' in Pakistan. It is shameful that in that situation doctors played the role of subordinate allies of drug MNCs.

OPPI Document

The Organisation of Pharmaceutical Producers of India (OPPI) prepared a document on the generic vs. brand name controversy. The arguments are so pathetic that they do not even merit a rebuttal. However one is forced here to respond to some of the points raised, as in future, in the campaign for abolition of brand names, the OPPI will continue to raise such points.

The OPPI document says that brand names ensure 'reliability of product' and 'total manufacture responsibility'.⁷ The point being made is obviously that big companies are more reliable and responsible. Just one example.

Out of a total 218 reported cases of substandard production of drugs, 135 were from 23 multinationals.⁸

When drug companies talk of 'reliability' and 'responsibility', it must be remembered that in 1923 the League of Nations officially pulled up Hoffman La Roche, founder of Roche, for being involved in trafficking in Cocaine. The same Roche, and Bayer, two 'responsible' MNCs today, carried out experiments of psychotropic drugs on pregnant Jewish women in concentration camps during World War II in Germany.

The document goes on to say that 'brands protect the doctor's rights to prescribe the medicine of choice to his patients'.⁸ In fact it does the opposite.

Ephedrine-Saline Nasal Drops, a drug useful in nasal bleeding and inflammation is not available in the market. In its place costlier and less effective 'brand name' substitutes like Nasivion, Otrivin, Distem, Latazol flood the market. Often single drug topical ointments are not available, while combination formulations with Steroids are freely available in the market. Such examples are endless.

Finally, the document makes the point that change to generics will stifle production of new drugs. First, the statement is untrue, otherwise no drug research would be taking place in the Soviet Union, where Brand Names do not exist. But what one is appalled by is the audacity of such a statement coming from OPPI. It comes in the background of the fact that big drug companies spend almost negligible amounts, as it is, on R&D. In fact the Lovraj Kumar Committee reported in 1977 that the outlays of 52 MNCs on sale promotion and administrative overheads were 33 per cent as compared to a mere 0.8 per cent on R&D. There are just a handful of drugs developed by drug companies in India. India and the whole Third World is used as testing centres for drugs developed by MNCs in their parent countries.

The situation is aptly summed up in a quotation from the text book of Pharmacology by D. R. Laurence : "It is unlikely that the common sense system of one name for one drug will be achieved in the near future as it seems to be impossible to reconcile uniformity with commercial enterprise".

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Unfair Practices in Marketing Adopted By Multinational Drug Firms in India

*J. S. Majumdar & Samir Kumar Das**

Introduction

Evidence of unfair marketing practices of the drug firms is increasingly coming to light. The World Health Organisation (WHO) has expressed concern and has suggested a Uniform Code of Marketing Practices throughout the world. The 3rd International Conference on 'Transfer and Development of Technology in the Developing Countries Under more Favourable Conditions in Pharmaceutical Industry' held in Belgrade in June 1979, recommended "monitoring and control of drug information published by the drug industry".¹

In India the Hathi Committee observed, "High pressure sales techniques coupled with distribution of medical samples on a liberal scale to the medical profession was their (MNCs') forte".²

It is surprising that the Drug Policy, 1978, completely ignored this particular aspect. The Report of the Steering Committee of the National Drugs and Pharmaceuticals Development Council (NDPDC), which made recommendations to the Central Government in formulating the New Drug Policy, has also ignored the proposal for Statutory Code of Marketing Practices. The Steering Committee, however, stated with anguish, "The Drug Industry's development is made difficult by frequent allegations of malpractices", and cautioned that, "The image of Indian Pharmaceutical Industry is not damaged by undeserved adverse publicity".³

Marketing of Drugs and Pharmaceuticals

Unlike other commodities, pharmaceuticals have a special feature of Marketing. For the sale of drugs and pharmaceuticals, marketing efforts are not directed to attract the consumer. The main thrust of marketing is directed in attracting and influencing the medical profession, who decide about the choice and selection for purchase of pharmaceutical products.

With the passing of time the marketing technique of pharmaceuticals has developed a high level of advertisement professionalism for ruthless exploitation of the patients. The medical profession unknowingly play their part in the overall marketing strategy of the drug firms. This is revealed in the words of the Divisional Marketing Manager of Glaxo Laboratories while addressing their Medical Representatives, "That you have achieved this without the help of any major antibiotics, is proof of your ability to generate prescription support. Doctors today are prescribing more and more Glaxo products due to your effective detailing from the folder. Modern teaching in consumer behaviour emphasises the point that in the absence of strong reinforcement, brand shift takes place. Reinforcement must be in the form of repeated stimulus. Please remember the primary stimulus is communication. Gifts and samples are only cues — a behavioural sign jargon, meaning secondary stimuli. Secondary stimuli will work only if primary stimulus is strong, that means complete and thorough detailing from the folder".⁴

The WHO Director General summarised these aspects in the World Health Assembly, "Drugs not authorised for sale in the country of origin — or withdrawn from the market for reasons of safety or lack of efficacy — are sometimes exported and marketed in developing countries; other drugs are promoted and advertised in those countries in indications that are not approved by regulatory agencies of the country of origin. Products not meeting the quality requirement of the exporting countries, including products beyond their expiry date may be exported to developing countries that are not in a position to carry out quality control measures. While these practices may conform to legal requirements, they are unethical and detrimental to health".⁵

Code of Marketing Practices

The WHO, therefore, noted, "Modern drugs are such potent weapons that the responsibility for their safe production and use can no longer be left entirely to manufacturer and prescriber".⁶

WHO further noted, "in most developed countries stringent regulations apply to the advertisement of drugs. In contrast, controls are lacking in majority of the developing countries".⁷

Therefore, "A proposal will be submitted to the Health Assembly on the possible introduction of international regulations concerning the labelling and advertising of pharmaceutical products".⁸

Such a proposal was not liked by the transnational drug firms. The powerful lobby of International Federation of Pharmaceutical Manufacturers Associations (IFPMA) opposed any move of WHO in this direction. IFPMA has even formulated a voluntary code so that an International Regulation could not be initiated by WHO.

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The proposal of WHO was also opposed by the US administration. The Surgeon General of the United States has said the US Government would oppose any move in the World Health Organisation (WHO) to introduce a marketing code for pharmaceutical drugs in developing countries.

Dr. C. Evertt Koop, attending the World Health Assembly, said, "the Reagan administration could not agree to proposal for such a code 'because laws of our land do not permit us to stipulate how an American Company will practise its trade in a foreign land'.⁹

In the face of such opposition from IFPMA and the US Administration, this issue could not even be added in the agenda of World Health Assembly, held in Geneva, in May, 1984.¹⁰

Marketing Practices in India

The Organisation of Pharmaceutical Producers of India (OPPI), which mainly looks after the interests of the TNCs, is an affiliate of the IFPMA. We tried to examine certain aspects of the marketing of the OPPI-Companies.

We collected copies of detailing folders, detailing booklets, medical "literatures" etc., from 11 multinational companies who are also members of OPPI and one Indian Company. These companies are Glaxo Laboratories, Eskayef Pharmaceuticals, Biological-E, Organon (Infar), Rousell, Wander, Parke Davis, U.S.V. Pharmaceutical, and Themis Chemicals.

We wanted to find out from the trend of advertisement of pharmaceuticals (mainly of OPPI Companies) how far they were implementing the voluntary Code of Marketing Practices of IFPMA. IFPMA assured that their member associations (including OPPI) would follow their voluntary Code of Marketing Practices.

Here we are not discussing the merits and demerits of the voluntary codes of IFPMA. Our study was limited to the nature of double standard in sales promotion activities adopted by the TNCs between their countries of origin and the Third World countries, with particular reference to India.

From our examination, it was revealed that the TNCs do not follow their own voluntary Code of Marketing Practices in India. Their practices are not only unfair but at times border on illegal activities.

In respect to printed promotional material, IFPMA's code states :

"Scientific and technical information shall fully disclose the properties of pharmaceutical products as approved in the country in question based on current scientific knowledge including

- The active ingredients, using the approved names where such names exist.

- At least one approved indication for use together with dosage and method of use.
- A succinct statement of the side effects, precautions and contra-indications".

All the printed promotional materials which we examined, and are reproduced in the following pages, failed to maintain the code as mentioned above. They failed to fully disclose the properties of pharmaceutical products based on current scientific knowledge, did not mention the active ingredients in many places. Indications were not connected with the dosage and method of use. A majority were without any statement of side effects, precaution and contra-indications.

The Code also states that, "particular care should be taken that essential information as to pharmaceutical products' safety, contra-indications and side effects or toxic hazard is appropriately and consistently communicated subject to the legal regulatory and medical practices of each nation. The word 'Safe' must not be used without qualification".

Just the opposite is being done by the drug firms. They use the word 'Safe' so frequently and without any qualification that almost every drug in the market is being promoted as a 'Safe' drug. It is an established practice in pharmaceutical marketing that the products' safety, contra-indication and side effects or toxic hazards are never communicated as a rule. This may happen as an exception only when the medical practitioner raises a question.

The code also says that "Statements in promotional communication should be based upon substantial scientific evidence or other responsible medical opinion. Claims should not be stronger than such evidence warrants. Every effort should be made to avoid ambiguity".

In the promotional communications, journals and text books were misquoted or purposely quoted out of context to create wrong impressions. The drug firms, in many cases, made claims of the merits of their products in an exaggerated way.

The code also states that "the information should be based on an up-to-date evaluation of all the available scientific evidence and should reflect this evidence clearly." Contrary to this the drug firms made statements which were not in accordance with all available scientific evidence. Sometimes, journals were quoted which have 20-25 years old references, thereby withholding current scientific information, revealing the hazards established through years of use of the drugs subsequently.

In the following pages we have dealt in detail with the evidence from which we have drawn the above conclusions.

Objective Information

IFPMA's code states that, "Information on Pharmaceutical Products should be accurate, fair and objective, and presented in such a way as to conform not only to legal requirements but also to ethical standards and standards of good taste". How far does the topmost MNC in the drug industry in India, Glaxo Laboratories, pass on information objectively and in an accurate way? The special campaign of Ostocalcium B₁₂ Syrup by the Company is revealing.

In the forwarding note, the Marketing Manager states, "you have a very powerful story to prove to the doctor that, for children's growth there is nothing better than Ostocalcium B₁₂ Syrup. The reason is simple : it provides both Calcium and Phosphorus. We will be telling the doctors this time that Phosphorus instead of impeding the absorption of Calcium as claimed by Sandoz actually improves absorption. Nature's source of Calcium is milk and in milk, Calcium is present with Phosphorus. It is Nature's formula. Likewise doctor's approved formula for growth is Ostocalcium B₁₂ Syrup where emotion has been married with logic. A powerful appeal"

How did they communicate this story to the doctors? It is reproduced in the following pages to give an example of communication of pharmaceutical products by MNCs.

Thus Sandoz while promoting Macalvit Syrup 'Scientifically' claims that Phosphorus impedes the absorption of Calcium while Glaxo with 'Scientific logic' claims that Phosphorus helps better absorption of Calcium! In fact Calcium absorption from dietary sources is not significantly altered by the presence or absence of Phosphorus.

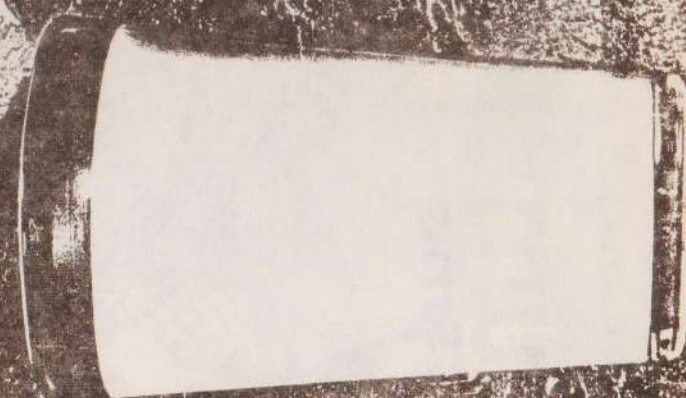
Moral for Truthful Representation

Eskayef Pharmaceuticals, the Indian name of Smith, Kline & French, a transnational of US origin, issued a circular to their Medical Representatives which is reproduced. In this circular the Company, wrongly quoting Milton Silverman of the University of California, states that he (Silverman) singled out three pharmaceutical companies including Smith, Kline and French, 'for showing responsibility in labelling and promotion'. In the same circular the Company vows to adopt the moral of "Truthful representation of products' merits and possible demerits".

It will be interesting to find out how far Eskayef in India are following this self-proclaimed moral, and how honestly they are following the code of IFPMA.

The literature (printed promotional material) on ESKACILLIN claims "A sure hit for the treatment of Respiratory Tract Infection, Skin and soft tissue infection, venereal and urological infection". The literature does

**Nature's best growth
formula—Milk.
Rich in Calcium,
rich in Phosphorus.
Absorbed better,
utilised better.**



Glaxo's growth formula...

Ostocalcium[®]

B₁₂ Syrup

"...retention is better if supplemental phosphate is also provided thus the phosphate salts may be preferable to others."

[Textbook of Medicine, 14th Edition, 1975 Besson & McDermott, (Cecil & Loeb), page 1829].

Rich in Calcium

rich in Phosphorus



Ostocalcium[®]

B₁₂ Syrup

**very tasty
Children love
to take it
every
growing
day**



neither make a truthful representation of merits nor does it mention anywhere the possible demerits. Further, the literature on ESKOLD fails to present scientific representation of facts. It also withholds the possible demerits of the drug.

The visual folder of Eskazine used for promotional communication to the medical profession misquotes journals in such a manner as if the articles referred to in the literature fully support the merits of "ESKAZINE". The exaggerated claims, absence of any reference to side-effects, contra-indication, etc., expose ESKAYEF's hollowness of its claims of truthful representation of facts. The ESKAZINE visual folder is being used for promotional communication in April, 1986. Why then does the Company quote references on ESKAZINE which are more than 25 years old? It is obvious that the Company is afraid of disclosing the serious demerits revealed in subsequent studies on Trifluoperazine (Generic name of Eskazine).

Exaggerated Claims

Most of the companies make exaggerated claims of the merits of their products. Sometimes the side effect of a drug is projected as an indication for its use. Invariably the claims are not substantiated by updated scientific information.

We studied the folders and literature of PERITOL (Cyproheptadine) of Themis Chemicals; DYSFUR (Furazolidone + Kaolin + Pectin) of Biological E; MELALITE (Combination of Hydroquinone and Glycerol Mono Para Amino Benzoate) of Nicholas Laboratories; WINSTROL and STROMBA (Stanazolol) of Winthrop; SEPTRAN (Co-trimoxazole) of Burroughs Wellcome; DEXATOPIC (Dexamethasone with chlorhexadine and androlone decanoide) of Organon, renamed as Infar, and NUGIN (Ibuprofen) of Glaxo Laboratories.

In all these folders and literature for promotional communication to the medical profession, the drug firms made exaggerated claims and various journals were misquoted.

PERITOL is available in the form of tablets, syrup and drops indicating that the drug can be used for children and infants also. The product (Cyproheptadine) is indicated for its anti-allergic properties. One of the side-effects of Cyproheptadine is weight gain. Now many of the drug firms, including Themis Chemicals, are promoting this product, converting the side effect as the main indication. The product is promoted for indiscriminate use even in children and infants. The side-effects, toxicity, precaution, contra-indication etc., are totally absent in the folder. No standard medical literature recommends the use of the drug for weight gain.



Osto calcium B12 Syrup

REF:

PSDT: 8/82

September 3, 1982

TO: All Professional Service Representatives

CC: Mr. E.P. Kapoor / Mr. G.D. Saini
RMs / ASMs

FROM: H.V. Iyer

SUBJECT: RESPONSIBLE DRUG PROMOTION

As marketing people we are often saddened by the long list of side effects and cautions that form part of the approved prescribing information for our products. These negative aspects of our products, we feel, should be kept to the barest minimum since they are detrimental to sales and needlessly dampen our enthusiasm while detailing to doctors.

Against this background, there is some cause for elation over an article titled "A double standard on Drugs?", which appeared in a recent issue of the prestigious TIME magazine (June 28, '82). This article is based on an eight-year study of drug promotion in third world countries by Pharmacologist Milton Silverman of the University of California at San Francisco. Melodramatically titled "Prescriptions for Death", the 172-page report diagnoses "an acute deficiency of social responsibility" on the part of the international pharmaceutical industry.

According to Silverman, the multinational drug companies practice a "blatant double standard" in selling their products to poorer nations. Side effects and warnings that are disclosed to the medical profession in industrialized nations are sometimes left out in the underdeveloped countries.

Doctors in these underdeveloped nations, says Silverman, are singularly dependent upon the data they receive from drug companies - either through their salesmen or through published drug information catalogues. Medical journals are often unavailable or unaffordable and physicians have little time for reading them since they may be seeing as many as 30 patients an hour.

While urging drug manufacturers to assume responsibility in this regard, Silverman singles out three pharmaceutical Companies - Merck & Co., Eli Lilly & Co. and SmithKline Beckman for already showing responsibility in labelling and promotion. Says he: "You can tell the truth and still make a decent profit".

As SK&F's accredited ambassadors in the field, the moral for you here seems to be - "Sales will never suffer through truthful representation of a product's merits and possible demerits." Establishing credibility is vitally important for any business, and reports such as these make us justifiably proud of being part of the SK&F family.

Best wishes,

[Handwritten signature]

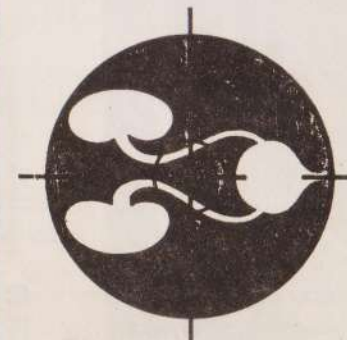
utilised better.

FROM SK&F

ESKAYCILLIN®

A sure hit for the treatment of

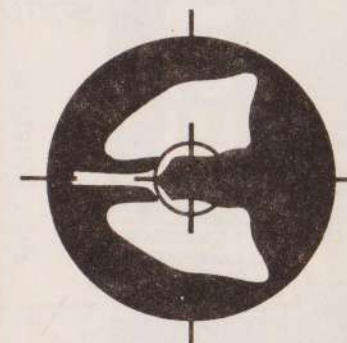
Venereal & Urological infections



Skin & Soft tissue infections



Respiratory tract infections



A famous fighter in the upper airways
against allergic rhinitis, sinusitis
and nasopharyngitis



ESKOLD® Spansule® Capsules

WHAT MAKES THEM GREAT:

P-51 Mustang

Engine — Packard built
Merlin
— V-1650-7
power plant
Speed — 433 mph @
30,000 feet
Range — 815 miles
Armament — Six .50-caliber
machine guns



ESKOLD® Spansule® Capsules

Ingredients — Phenylpropanolamine
HCl 50mg.
— Diphenhydramine HCl 5mg.
Speed — Prompt relief of runny
nose, stuffy nose,
sneezing and watery eyes.
Range — Up to 12 hours of
continuous relief.
**Other
features** — No symptom breakthrough.
— No forgotten or missed doses.
— Convenience of b.i.d. dosage.



Presentation: In bottles of 6 capsules

SKCF
ESKAYEF
PHARMACEUTICALS
Eskazine® (Lunafin)
Licensed user of Registered Marks®

Concern

'ESKAZINE' Vs Benzodiazepines

If one of the benzodiazepines hasn't worked
the chances are the others won't either.

LOW DOSE **ESKAZINE®** 2-4 mg/day

The effective anxiolytic

A review of some of the open trials on the use of low doses of 'Eskazine' in the treatment of anxiety shows that a fair to excellent response was noted in the majority of patients.

In most cases improvement was seen during the first week of treatment, often within the first one or two days.

LOW DOSE **ESKAZINE®** 2-4 mg/day **Minimal side effects, minimal drowsiness**

A retrospective survey of adult patients given up to 4 mg of 'Eskazine' a day revealed that over 90% of them had experienced no side effects of any kind. There was a notable absence of drowsiness and a very low incidence of extrapyramidal symptoms.

'Used in low dosages it ('Eskazine') does not cause daytime drowsiness or inhibit normal interest and initiative.'

Gearren, J. B., 1959, Diseases of the Nervous System, 20, 66.

LOW DOSE **ESKAZINE®** 2-4 mg/day

Dependence is not
a problem in
long-term therapy

Even though it has
been in use for almost
twenty years,
'Eskazine' has not
been shown to produce
dependence.

LOW DOSE **ESKAZINE®** difference
makes it an effective alternative for the
non-responder

*See full prescribing information

In the folder on DYSFUR the company not only claims its efficacy for prompt control of diarrhoea but also claims that it has the property to 'Prevent dehydration'. Such promotion is fraught with danger as the routine measures for rehydration in diarrhoea patients may be neglected under the misconceived notion that DYSFUR would prevent dehydration. The company does not care to produce any scientific evidence in support of such tall claims. None of the ingredients of DYSFUR namely, Furalodine, Kaolin or Pectin can prevent dehydration. Such promotion is not only unethical, but criminal.

For MELALITE, Nicholas Laboratories present quotations from Goodman and Gillman in such a manner that an impression is created as if Hydroquinone is an effective skin-lightening agent. The product is promoted for developing fair complexion. The serious side effects after prolonged use, like Leucoderma, is not mentioned. On the contrary it is claimed that the drug is "safe" for use.

Winthrop markets Stanazolol through two different companies, WINSTROL — through CFL Pharmaceuticals, and STROMBA — through Winmedicare (P) Ltd. These two Companies are promoting the same drug for different indications. WINSTROL is claimed to have properties for stimulating appetite and proper protein metabolism, for raising haemoglobin level, shortening convalescence period, for minimising the chance of relapse, secondary infection and for countering the side effects of Corticosteroids. WINSTROL also claims improved mineral retention, restoration of Phosphorus and Calcium balance, repair of bone matrix and improved wound-healing, etc.

STROMBA on the other hand claims to correct negative Nitrogen balance when given with adequate calories and proteins, reverse the process of muscular wasting and weakness and accelerate healing of fracture and wounds.

Burroughs Wellcome is now promoting SEPTRAN for "Success in sexually transmitted diseases". It quotes two obscure studies involving just 88 and 35 patients respectively, to give an impression as if their claims were supported by scientific evidences. No standard text book lists Co-Trimaxozole (i.e. Septran) among the first line drugs for any of the four conditions listed in the folder i.e., Gonorrhoea, Chancroid, Granuloma Inguinale or LGV.

In their visual folder, Organon recommends DEXATOPIC as 'the safe first line treatment for common skin disorders'. Obviously they cannot substantiate their claims scientifically and hence no scientific evidence is quoted.

In April, 1986, Glaxo Laboratories launched promotion of NUGIN, a simple Ibuprofen Tablet, as a safe, effective and unique drug for all types of pain and fever with guarantee of 30 times more effective result than

Aspirin in relieving pain and 20 times more effective in fever. Glaxo Laboratories, the topmost sellers of Pharmaceutical products in India, did not feel it necessary to substantiate its claims with scientific documents. In fact, the claims are so absurd that it would be impossible to do so.

Misleading Reference to Medical Text Books, Journals and Authorities

Not only are journals quoted out of context to create an impression that supports their exaggerated claims, but some drug firms refer to text books, journals and authorities to blatantly misrepresent facts. In the earlier paragraphs we explained how the drug firms try to support their exaggerated claims through ambiguities and by misquoting. Here are examples where the drug firms straightaway resorted to misrepresentation of facts.

We have examined the folders and literatures of SPERT of Wander, a subsidiary of Sandoz; AQUAVIRON B₁₂ of Nicholas Laboratories; GESTANIN of Organon; CORTASMYL of Roussel, POLYCROL FORTE of Nicholas and ORABOLIN of Organon.

Wander, highlighting its Swiss origin claimed that SPERT is an "original research product". One may well question as to what original research is involved in a product which is nothing more than pre-digested protein food! The company not only misquotes WHO and FAO, they also misrepresent a study by Central Food Technological Research Institute (CFTRI), Mysore.

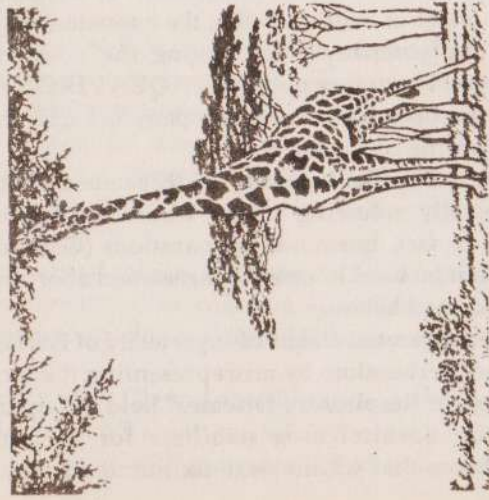
AQUAVIRON B₁₂ (containing Testosterone and Vit. B₁₂) is promoted amongst other indications in cases of delayed healing of fractures and Diabetes Mellitus. But the quotations in support of these claims from journals and textbooks do not confirm these indications. For example, in case of impotence in large number of male diabetics, the quotation suggests trial of Testosterone. But the company is promoting the product for treatment of Diabetes Mellitus! In another quotation AQUAVIRON B₁₂ is suggested for use in senile osteoporosis but the company is highlighting the indication "in delayed healing of fractures"!

GESTANIN is recommended by the company in threatened abortion and premature labour, wrongly referring to the studies of School of Medicines, Madrid, Spain. In fact, hormonal preparations (Gestatin is such a preparation) should not be used in cases of threatened abortions as they can lead to birth of deformed babies.

Similarly, Roussel makes exaggerated claims of superiority of Cortasmyl compared to Salbutamol and Terbutaline by misrepresenting the facts in referring to the "5th Congress of Respiratory Diseases" held at Jaipur.

Nicholas Laboratories use Sorbitol as a stabilizer for its antacid POLYCROL FORTE. It claims that within next six months potency is

The Only True Appetite Stimulant

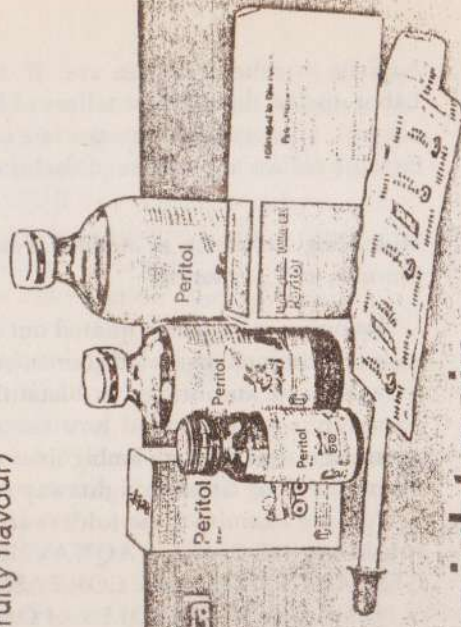


Peritol Tablets
(Cyproheptadine tablets)

Alcohol FREE
Peritol Syrup and Drops
(New improved fruity flavour)

- Stimulates natural desire to eat more
- Promotes symmetrical weight gain
- Increases nutritional intake
- Enhances healthy constitution

Peritol guarantees weight gain



Immediate control of
Diarrhoeas &
prevention of
dehydration

Tasty
anti diarrhoeal
for
children

Rx **DYSFEUR**



Controls
Diarrhoea fast
prevents dehydration



A new, effective, rational therapy for hyperpigmentary skin conditions like

- * Chloasma
- * Residual hyperpigmentation
- * Freckles, Lentigines
- * Post-inflammatory hyperpigmentation
- * Skin blemishes
- * Patchy hyperpigmentation

The logical and scientific combination

Hydroquinone — 2.0% w/w Effective and safe skin-lightening agent

Results with hydroquinone are good enough to help the majority of patients become less self-conscious about their abnormality. Hydroquinone is safe for local use" Goodman and Gilman 6th Edition p 959

Glyceryl Mono Para Amino Benzoate — 2.8% w/w

- Excellent sunscreen agent
- Cosmetically highly acceptable

6 Outstanding Benefits

- Effectively lightens the skin improving complexion and appearance
- Dual complementary action resulting in faster lightening effect
- Protects the skin from darkening, sunburns and premature ageing effects of the sun
- Practically non-irritant and well tolerated
- Safe for use
- Excellent patients' compliance

MELALITE cream
The double action remedy for hyperpigmentation



Nicholas
Laboratories
India Limited
Deonar, Bombay 400 068
Regd. Trade Mark

TROMBA — brand of stanozolol stores nitrogen balance and protein synthesis.

in debilitated, chronically ill patients and the elderly:

- corrects negative nitrogen balance when given with adequate amounts of calories and protein.
- reverses the processes of muscular wasting and weakness.¹

in post-surgical and other immobilised patients:

- accelerates healing of fractures and wounds.
- favourably influences cutaneous scarring.²
- speeds up rehabilitation.³

in post-menopausal osteoporosis:

- significantly decreases bone resorption, thereby reducing local bone pain.⁴
- beneficial and substantial effects of Stromba were demonstrated in a 2-year controlled trial in 38 osteoporotic females (21 treated, 17 controls), each with at least one spinal compression fracture. With Stromba 2 mg t.i.d. plus 1 gm dietary Calcium.⁵

Treatment group	No. of Patients	Anabolic Regimen	Oral Calcium	Increase in Total Body Calcium	Incidence of New Fractures
21	21	Stromba 2mg. tab. t.i.d.	1gm.	4.43%	none
Control group	17	Placebo	1gm.	0.37%	3

STROMBA IS MORE EFFECTIVE
STROMBA has the highest SPAL (Steroid Protein Activity Index) amongst the commonly used anabolic agents.⁶

Anabolic Steroids	Dosage (mg/day)	Average SPAL
Testosterone Propionate	10-25	+6
Methandienone	5-30	+16
Stanozolol	6-12	+29

STROMBA

— counteracts negative nitrogen balance resulting from clinical situations, such as prolonged steroid therapy, chronic diseases, surgical conditions, general debility, burns, fractures and trauma etc.

— ensures highest protein synthesis amongst the commonly used anabolic steroids.

STROMBA IS SAFER

STROMBA has the highest anabolic/androgenic ratio and therefore the least utilising potential amongst the commonly used anabolic agents.⁷

Anabolic/Androgenic Ratio*	
Testosterone Propionate	1
Methandienone	1
Ethylestrenol	20
Stanozolol	100

*THE HIGHER THE RATIO, THE LOWER THE ANDROGENICITY

Winstrol[®]

Stanozolol 2 mg.

Re-aligns the metabolic processes

- in acute illness
- in cases of hampered protein assimilation
- in severe burns and after surgery
- in trauma and wasting diseases

Winstrol[®] mediates proper utilization of ingested protein, steps up protein synthesis, restores positive protein-nitrogen synthesis

- in cases of malnutrition
- in asthenic and debilitated patients
- in the elderly

Winstrol[®] stimulates appetite and protein intake, reverses protein catabolism, induces weight gain and builds up body resistance

- in post-surgical cases
- in patients of trauma and fracture
- in severe burn cases

Winstrol[®] improves mineral retention, restoring calcium and phosphorous balance, aids in repairing bone matrix, facilitates wound healing, speeds up recovery

- in patients requiring prolonged rest due to parasitic or infectious diseases
- in patients of debility, wasting or chronic disease
- in patients on long-term steroid therapy

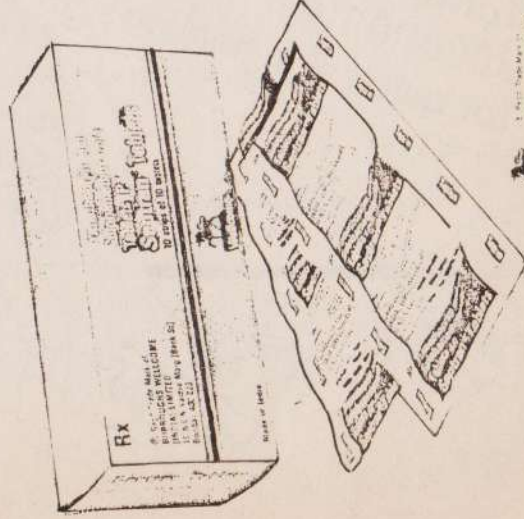
Winstrol[®] raises haemoglobin levels, shortens the period of convalescence, minimizes the chances of relapse/secondary infections and counters the side effects of corticosteroids

Septan

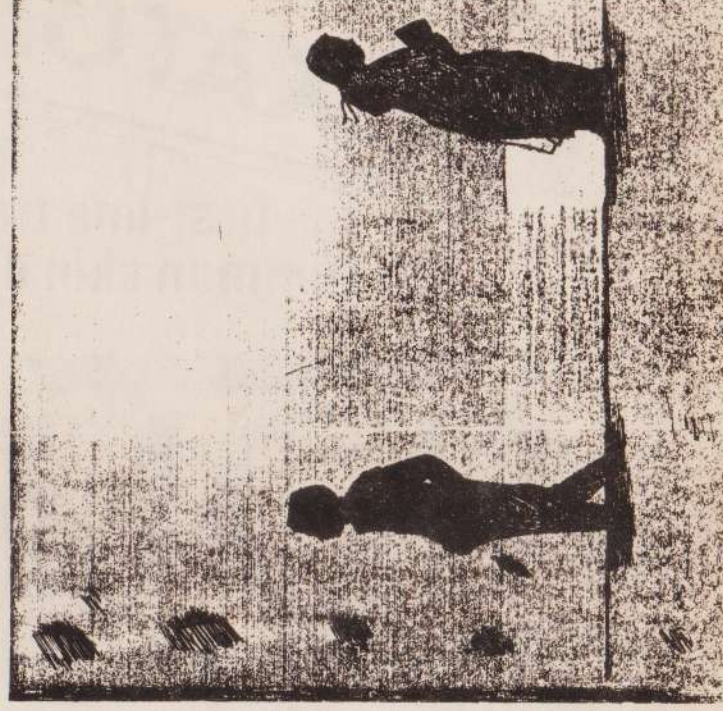
Success in sexually transmitted diseases

Indications:

- Gonorrhoea
- Chancroid
- Lymphogranuloma venereum (LGV)
- Granuloma inguinale



*When
bacterial infection
affects
their relationship*





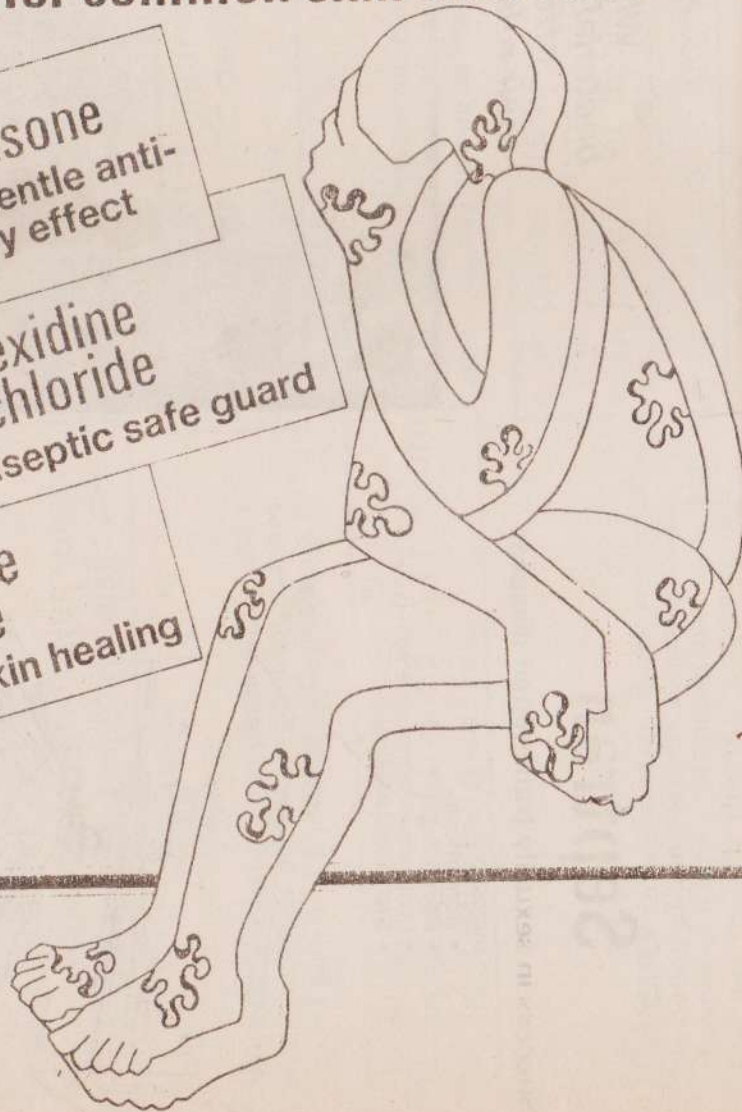
DEXATOPIC

The safe
first-line treatment
for common skin disorders

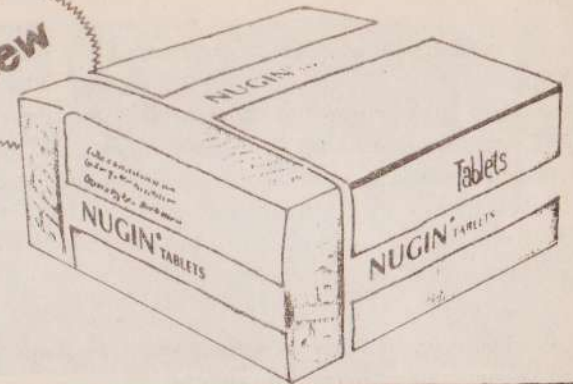
Dexamethasone
for proven gentle anti-
inflammatory effect

Chlorhexidine
hydrochloride
for antiseptic safe guard

Nandrolone
Decanoate
for quick skin healing



Unique
-acts
at the
peripheral
site of
PAIN



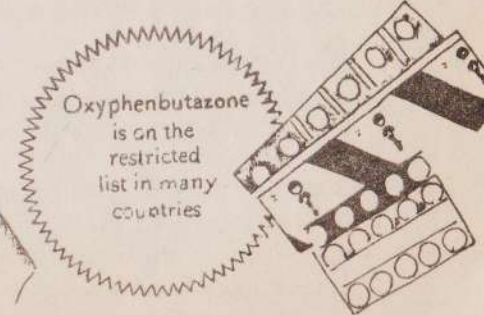
NUGIN

Effective

- * 30 times more effective than Aspirin in relieving PAIN
- * 20 times more effective in bringing down FEVER
- * Significantly better than Paracetamol

Safe

safer than
Aspirin
Analgin
Oxyphenbutazon
Paracetamol



Oxyphenbutazone
is on the
restricted
list in many
countries

reduced by 60% in other antacids and 10% in POLYCROL FORTE. To support their claims they quote Eastern Pharmacist. Such a claim is contrary to the rules laid down under Drugs and Cosmetics Act.

Organon quotes a text book in such manner as if ORABOLIN drops are recommended to check protein loss which is common in diseases like Tuberculosis, Typhoid, Influenza, etc. In fact Orabolin contains Anabolic Steroids. Their use in children can cause serious growth disorders and can cause deformities in the genitalia.

Withholding and Misrepresentation of Information of Dosages, Side Effects, Precautions

Some of the printed materials for promotional communication to the medical profession distorted or deliberately withheld dosage and statements of side-effects, precautions, etc.

In the folder for promotion of CELIN, Glaxo Laboratories promote Vitamin C in a dose of 500 mgs three times a day. No text book suggests Vitamin C in such high dosages even for therapeutic purposes. Vitamin C in high doses may cause hyperglycaemia¹². Further it may lead to many other serious side effects like formation of urinary stones.

In the PAVULON folder, Organon claims "Remarkable cardio-vascular stability" but forgets to mention that in higher doses not only cardio-vascular stability is disturbed, but it may have other disastrous consequences. The folder is silent on dosage, side effects and contra-indications. For this purpose they only ask the medical practitioners "Refer product safeguards".

For BASOQUIN of Parke-Davis, the printed literature does not contain contra-indications, side effects and precautions. BESTOPHEN (containing Oxyphenbutazone) of Biological E is indicated only for severe arthritis as Oxyphenbutazone is known to have many hazardous side effects. But the company is promoting the product in "painful inflammation" even in April 1986, without mentioning the side effects, contra-indication, precaution and even the dosage.

Standard of Ethics and Good Taste

The IFPMA code mentions that the pharmaceutical companies should maintain "Standard of ethics and good taste".

Glaxo Laboratories present a segmentwise detachable cardboard figure of a woman for the "BETNOVATE GAME" for advertisement of BETNOVATE group of skin ointments. Such type of promotional activities not only violates all limits of unethical standards but also vitiates the entire relation of the industry with society.

Glaxo Laboratories have also started promoting Pharmaceutical products

SPURT[®]

AN ORIGINAL RESEARCH PRODUCT
OF WANDER

— a company of Swiss origin —

FILLS THE GAP AND EMERGES
as an ideal protein food supplement

- Net Protein Utilisation is 100%
- Protein will be fully utilised for body-building activity because of the quality of protein and the ideal protein-calorie ratio
- Better weight gain because of better protein efficiency ratio
- Enriched with vitamins, calcium, iron and zinc as per WHO recommendations
- Tastes good! Better patient-compliance
- Cost of therapy per day is more economical

1

Rapid regaining of normal strength & quicker recovery during

2

Faster all-round growth for growing children

3

Better development of the foetus; better and longer lactation

4

Ideal protein food supplement for busy people with irregular food habits

SPURT a superior protein food supplement brings real SPURT in the life of your patients

CFTRI, Mysore, studies confirmed that while

each gramme of protein

THE
S.

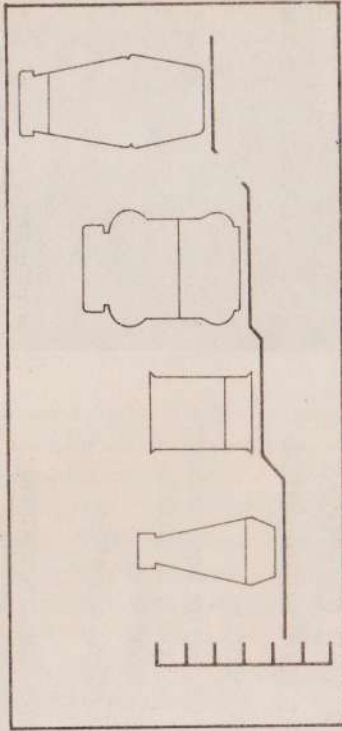
Assimilated and Fully Utilised

for

Body-building and Repair

**the protein in other products is
only Partially Utilised**

SP-67
has a superior
Protein-efficiency
ratio



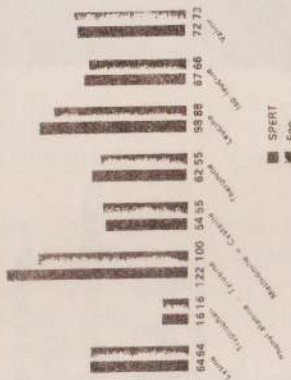
The protein in **SEET** is superior
(fully assimilated and utilised).

because:

(a) Spert not only contains all the essential amino acids, but the amino acids are present in the right proportion

(b) The protein in Spert provides optimum therapeutic benefits because its amino acid profile matches that of the ideal reference protein, hen's egg (100% biological value as recognised by WHO/FAO)

(c) Further, protein-calorie ratio (PCR) of Spert is near to ideal. Therefore, the protein in Spert will be utilised for body-building which is more desirable than wasting it as a source of energy.

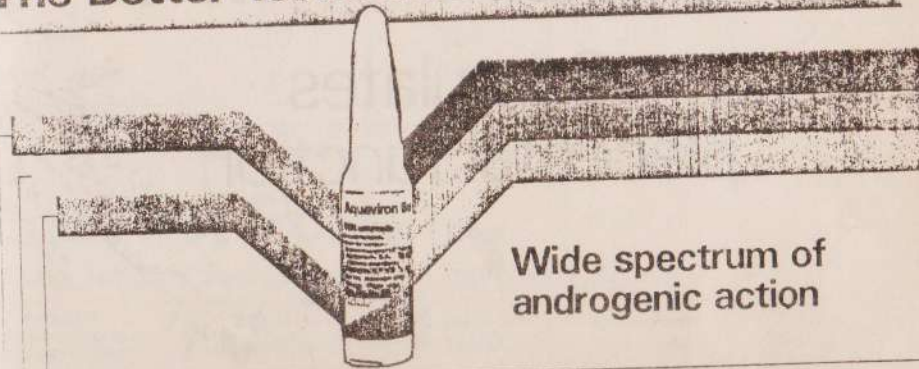


Amino acid profile of Spert and hen's egg.

(d) Taste is a vital factor in increasing patient's compliance. Spert is really tasty! This is not the case with other protein preparations, especially liquid proteins.

Aquaviron B12

The Better Testosterone + Vitamin B₁₂



Wide spectrum of androgenic action

In male climacteric, organic impotence, premature senility

"Testosterone preparations generally have a stimulant influence raising the general well-being and reducing fatigue, especially in older individuals; such tonic effects *per se* may stimulate sex impulses"²

Simple Dosage: 1 to 2 ampoules every week, diminishing the frequency as condition improves

- In oligospermia

"30 out of 38 patients (78%) showed marked improvement in sperm count and motility"¹³

Simple Dosage : One ampoule every week for 6 weeks, can be repeated after four weeks if necessary

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"The therapeutic effectiveness of Aquaviron B12 in the absence of significant side effect makes this preparation suitable for clinical use in senile osteoporosis"⁴

Simple Dosage : 1 ampoule every day for two weeks

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"...impotence, probably reflecting a disturbance of automatic function occurs in a large proportion of male diabetics; testosterone is worth a trial in cases of impotence..."⁵

Simple Dosage : 1 ampoule twice a week for about 6 weeks, thereafter diminishing the frequency

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GESTANIN

Stimulates
placental function

GESTANIN

in threatened abortion, premature labour ⁽¹⁾

(Specially in cases of placental insufficiency)

	Patients	Abortions	No. of Newborns
Trimester I	297	90	207 (70%)
Trimester II	37	1	37* (97.2%)
Premature Labour	41	2	39** (95.1%)
Total	375	93	283 (75.4%)

(1) Prieto et al, School of Medicine, Madrid, Spain, Clinical Therapeutics, Volume 3, No. 3, 1980.

* One set of twins included

** One Caesarean section

Polycrol[®] Forte Gel

★ Effective formulation ★ Excellent taste ★ Economical price

Product (concentrations in mg per 5 ml)	Methyl-polysiloxane	Magnesium Hydroxide	Aluminium Hydroxide	Total antacid
Polycrol Forte Gel	125	100	425	525
Digene*	12.5	92.5	425	517.5
Gelusil MPS	50	250	250	500
Mucaine*	—	98	291	389

* In addition: Digene contains Sodium Carboxymethylcellulose 50 mg
Mucaine contains Oxethazaine 10 mg

Polycrest[®] Forte Tablets

★ Strong action ★ Positive relief ★ Convenient dosage

Product (concentrations in mg per tablet)	Methyl-polysiloxane	Magnesium Hydroxide	Aluminium Hydroxide	Total antacid
Polycrest Forte	125	400	400	800
Digene**	10	25	300	375
Gelusil MPS	50	250	250	500
Diovol**	25	100	240	400
Almacarb**	40	—	325	375

** In addition: Digene contains Magnesium Aluminium Silicate 50 mg
Diovol contains Magnesium Carbonate 60 mg
Almacarb contains Magnesium Carbonate 50 mg and Deglycyrrhizinated Liquorice 380 mg

Clinical Evidence

The RIGHT dose of activated methylpolysiloxane for effective flatulence control

The Extra Pharmacopoeia by Martindale 28th Edition, 1982, p. 1069

Doses of up to 2 g (activated methylpolysiloxane) daily have been used often in conjunction with antacids such as aluminium hydroxide"

Drug Treatment—Principles and Practice of Clinical Pharmacology and Therapeutics by Graeme S. Avery, 1976, p. 519

"Most dosage schedules used are probably too small; a dose of 125 to 250 mg methylpolysiloxane 4 to 6 times daily is more effective"

Sorbitol for excellent stability

Eastern Pharmacist, April 1977, Vol XX No. 232, p. 125.

"Sorbitol proves a good stabilizer for Aluminium hydroxide gel. During the 6 months ageing period, sorbitol containing gels lost less than 10% of their acid consuming capacity compared to a loss of 60% for identical gels without sorbitol"

Nicholas

Nicholas Laboratories India Limited

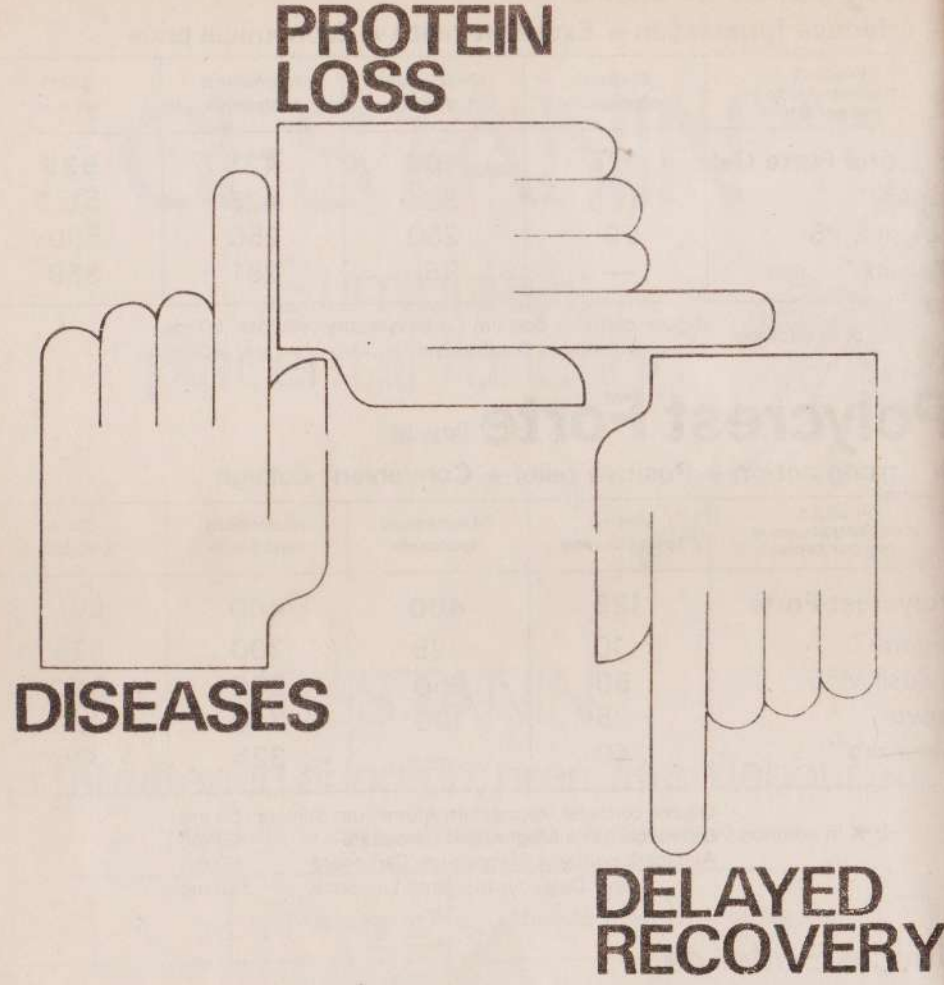
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Use only of a Registered Medical Practitioner or a Hospital or a Laboratory

"...up to 300-400 gms. of body protein may be destroyed daily specially in diseases like tuberculosis, typhoid, influenza etc."

—Prof. Best & Taylor in "The Physiological Basis of Medical Practice" P. 1425 8th Ed.



Comparing

cortasmyl &
 β_2 Sympathomimetic Agents
 (Salbutamol/Terbutaline)

Show that

— **cortasmyl**

produced greater improvement in lung function indices (FEV₁, FVC, Peak Flow)

— **cortasmyl**

reduced the frequency and severity of acute episodes to a greater extent

— **cortasmyl**

had lesser side-effects

&
 the overall response to treatment was better with

cortasmyl

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β_2 Sympathomimetic Agents
 (Salbutamol/Terbutaline)

cortasmyl

induces the
 synthesis of
 lipomodulin

stimulates
 β_2
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inhibits
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blocks
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↑ level
 of
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Blocks release of asthma mediators

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normal diet

For prompt return
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HASTENS RECOVERY

- ♦ CHECKS PROTEIN LOSS & PROMOTES PROTEIN SYNTHESIS
- ♦ HELPS REGAIN LOST WEIGHT
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- ♦ MINIMIZES RISKS OF RELAPSES & SECONDARY INFECTIONS

Composition :
Each 1 ml. contains :
Ethylloestrenol B.P. 2 mg.

Presentation :
Bottles of 5 ml.



ORGANON (INDIA) LIMITED
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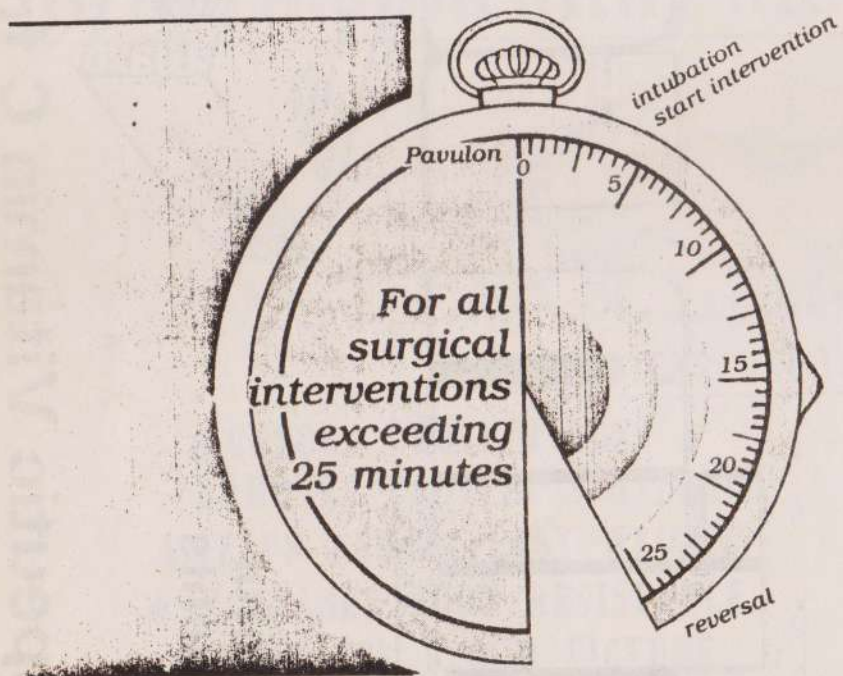


not chewable
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sweetening agents

The Therapeutic Vitamin C from *Glaxo*

PAVULON

FOR
COMBINED INTUBATION AND
MUSCLE RELAXATION



PAVULON

- * Minimal ganglion blocking activity
- * Does not release histamine
- * Remarkable cardio-vascular stability

Composition :

One single injection of 2 ml. contains
Pancuronium Bromide 2 mg. per ml.

For contraindications, warnings,
precautions & adverse reactions:

REFER PRODUCT SAFEGUARDS

BASOQUIN[®] SUSPENSION

SINGLE DOSE CONVENIENCE

for treatment of clinical
attacks of malaria

for prevention of clinical
attacks of malaria



DOSAGE

Treatment of acute attacks
of malaria

BASOQUIN SUSPENSION

AS A SINGLE DOSE

Children under 5 years of age:
5 ml. (one teaspoonful)
Children from 5 to 15 years of age:
5-15 ml. (1-3 teaspoonfuls)

AS A SUPPRESSIVE

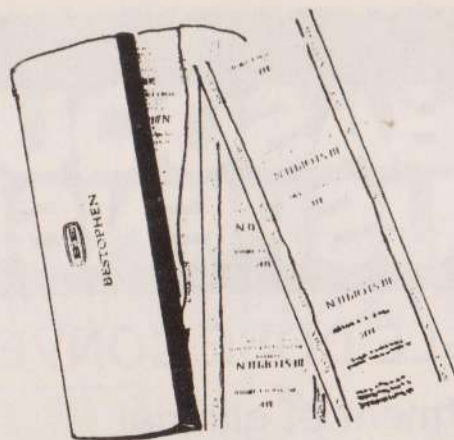
The above dosage should be taken as a
single dose every two weeks

PARKE-DAVIS

® Regd. Trade Mark - Regd. Users -
Parke-Davis (India) Limited,
Saki Naka, Bombay 400 072

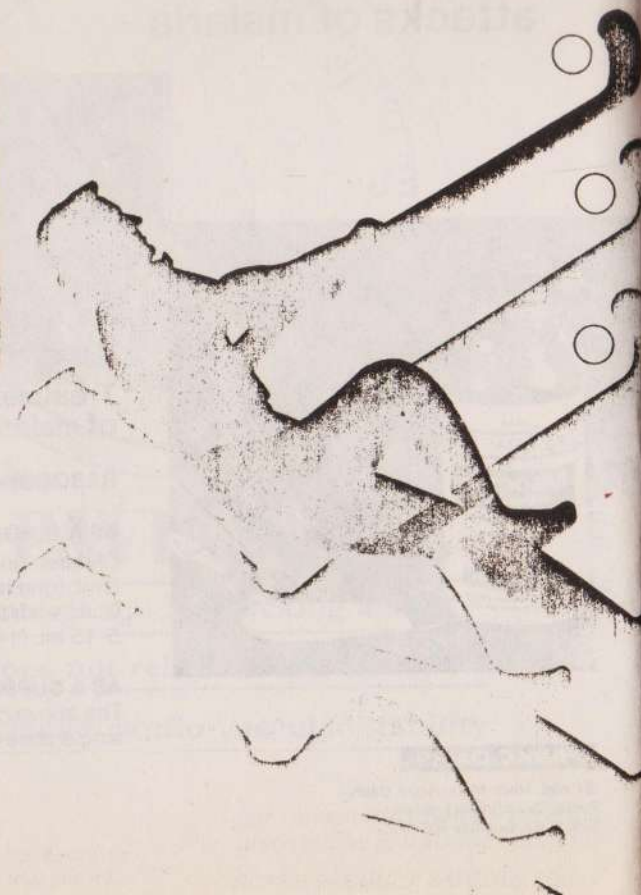
SUPERIOR BESTOPHEN TABLETS

IN PAINFUL
INFLAMMATIONS



**BESTOPHEN
TABLETS**

Superior to single
ingredient therapy.



to Chemists and Druggists. For this purpose they have brought out special folders. In one of these the Company requests Chemists to give CELIN 500 whenever Vitamin C is prescribed with inducement of more profits. The folder also conveys the message to the Chemists to sell PIRITON for all types of cough as an O T C (Over-the-Counter) product.

Are these the standards of ethics that the Multinational Pharmaceutical Companies are supposed to adopt in promoting their products? Where is their highly advertised standard of ethics and good taste? And where is the scientific approach in promotion of drugs which the MNCs claim to adopt? When U S V Pharmaceuticals promote VIGLOBIN as the "only cardamom flavoured haemoglobin tonic", and Rousell promotes ELSOMA tonic for its 'Honey-base' having distinct advantage, we wonder as to what extent the rot has penetrated the entire set-up.

Promotion of Banned Drugs

Manufacturing of 18 fixed dose combination of drugs were banned by the Government of India in September 1982. One such combination is "Fixed dose combinations of Steroids for internal use except combination of steroid with other drugs for the treatment of Asthma". But the detailing folder of Glaxo Laboratories for the campaign period December '82 — January '83 promoted BETNETON, a combination of Steroid Beta-methasone with anti-histamine for all types of allergic conditions. Such a combination was banned for their hazardous effects. With full knowledge of this ban and the hazardous effects of the drug, the Company continued promoting this product in allergic conditions.

Conclusion

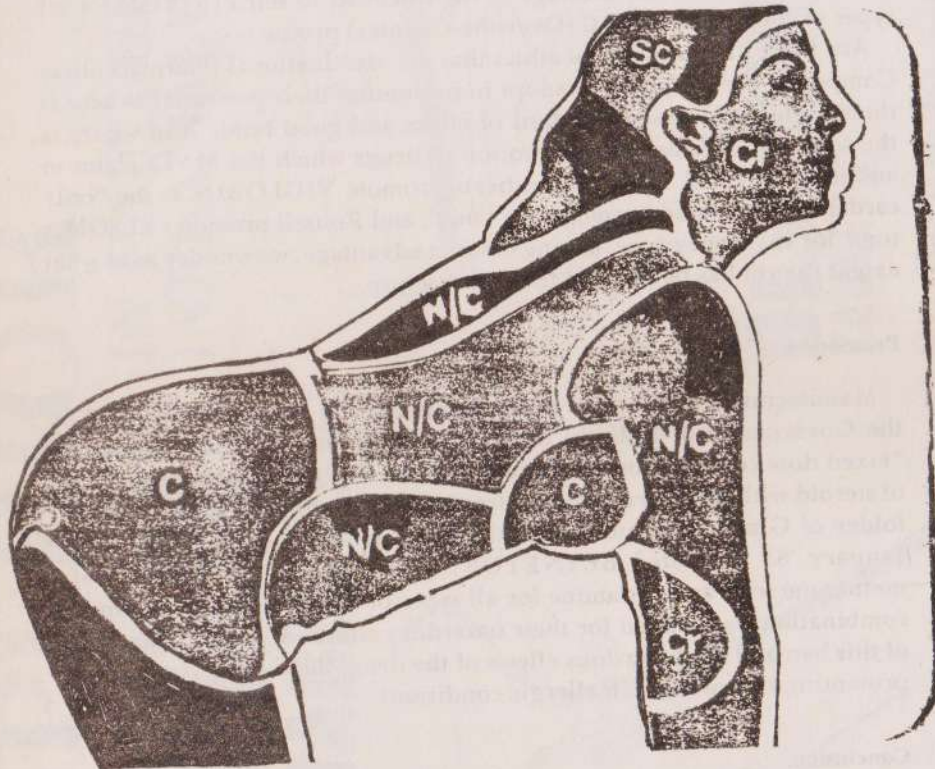
In the foregoing pages we described the methods adopted by the drug firms in promoting their products. Our conclusion is that they, more often than not, resort to unfair marketing practices.

We have studied the situation in MNCs mainly. But such unfair practices are not confined amongst the MNCs only. Unfortunately, this has become the general all-pervading practice in the entire industry.

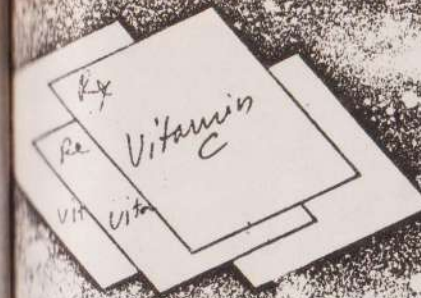
In 1973 Glaxo started a rat-race by discarding printed literatures and introducing the concept of folders and detailing with gimmickry of light and sound, special gifts and special campaigns, etc. With such methods Glaxo could outbid Pfizer and Sarabhai, and emerged as the Number One Pharmaceutical Company in India. Obviously, this has had a fallout. The entire industry joined the race.

We did not include in our study other areas of unfair marketing practices like sampling, gifts, organising seminars and symposia, etc. These matters

Glaxo



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GAME**



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prescription
Vitamin C

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COUGH
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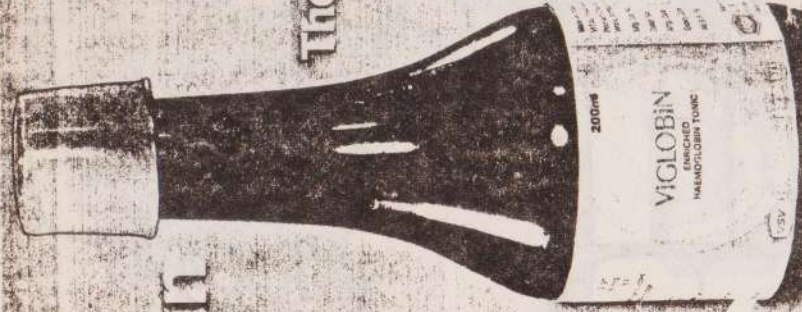


please recommend
with confidence
to your customers

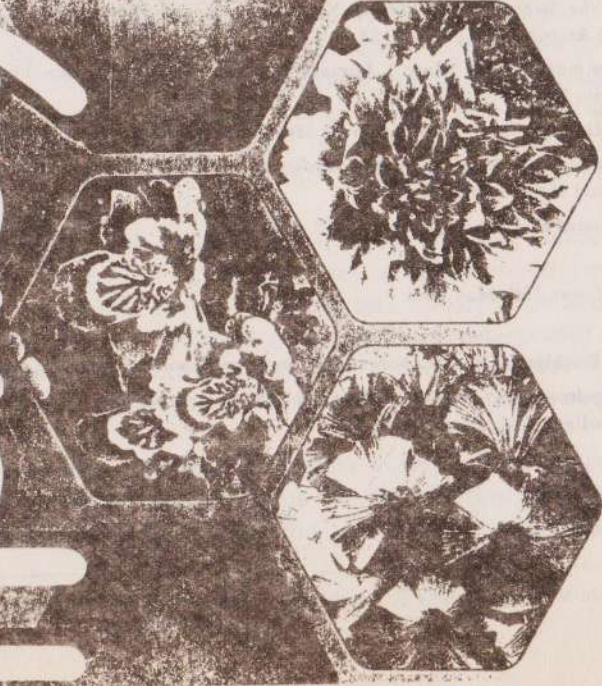
PIRITON
GLAXO EXPECTORANT

Yes! Viglobin

The only cardamom flavoured
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honey



in a TONIC
with a difference

elsoma

honey-based tonic
for improved
general health



Nutritionally wholesome

Appetite stimulating

Natural
Energy

ROUSSEL

are subjects for separate studies. However from evidences which are already available, there are indications that the conclusions would not be different in these studies.

The powerful lobby of MNCs and the U S Administration have forestalled the attempt of WHO from even discussing a code of marketing practices in the World Health Assembly. The IFPMA's voluntary code was only for public consumption and not for implementation by their member Associations.

The drug laws do not have the teeth to prevent such practices. The Drugs and Magic Remedies (Objectionable Advertisement) Act 1954 is too insufficient to control the situation.

What is required is a statutory Code of Marketing Practices which should be adopted for the drug industry without any further delay.

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Marketing of Medicine (Parasitology for Profit)

Amitava Guha*

Marketing Concept

Along with the development of capitalism, production relations have become complex without losing their basic characteristics. Prior to this, society used to produce and consume according to its needs and often need was more than production. Locus of commodity was simple, from production to consumption. This unidirectional locus still exists for all essential commodities for which technological innovation and productivity are the main concern for generation of more surplus value. Along with the development of monopoly capital, the simple co-relation of production and consumption gets converted to the development of market relation as the substitute for individual and community relation. The social structure is such that relations between individuals and between social groups do not take place directly, but through the market as relations of purchase and sale.

Preponderance of market relation over human relation is thus the genesis of marketing management. Therefore it does not flow as a felt need of society, but is a vehicle for thrusting commodities on the people to generate more profits. Marketing management is hence not the outcome of simple production relations. It serves to control production so as to suit the generation of surplus value for the recurrent generation of monopoly capital. It has no social contribution.

Prior to the existence of monopoly capital, production and consumption through trade was direct. In the next stage of development, processes like designing, calculations, record keeping etc., enhanced productivity and profit. The concept of marketing gave rise to a survo-control mechanism for consumption, and super profits thus generated ensured production and its planning. In other words, Marketing Management is the parasitology of profit.

This phenomenon is absent in socialist society, where the commodities reach the customers directly from the production site through the distribution channels. As opposed to Capitalist Countries, where demand

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generation is the yardstick of production, Marketing Management in Socialist Countries serves as an instrument of demand estimation.

Development of Marketing Management in India

Immediately after Independence, marketing techniques were not employed in India till the development of industries and flourishing of finance capital. Boyd and Westfall observed in 1950: "Selling effort is very limited among Indian wholesalers. The travelling Salesman scarcely exists"

But the Indian market, even then, had tremendous potential. Professors Lypson and Lamount observed in 1969: "The knowledge that 5 per cent of India's 520 million population, or 26 million people, have income that give them the buying power of the average American should suggest to marketers that it is imperative for them to get in early in India's industrialisation and market development. Such a market size in fact represents an affluent market that is just a little larger than the Canadian Market".

This was clearly understood by the drug multinationals and the growth of the drug industry in India has been phenomenal. Today 70 per cent of the market is controlled by 63 multinationals. Irrespective of the guise of Indianisation, these 63 foreign companies are financially and administratively controlled by their headquarters situated outside India.

What Drug Companies sell

"India is a classical example among under-developed countries where

Per cent Share of Different Groups of Drugs

	Sale (Crores) (Rs.)	Per cent of total market
Systematic Antibiotics	249.02	21.15
Vitamins, Tonics, Mineral	187.78	15.95
Supplement Tonics, etc.		
Cough & Cold preparations,	55.40	4.70
Nasal decongestants etc.		
Anti-parasitics	46.78	3.97
Analgesics	44.29	3.76
Antacids	38.17	3.64
Anti inflammatory & anti-Rheumatics	53.06	4.50
Anti T.B. drugs	30.39	2.50
Enzymes	24.69	2.10
Sex hormones	23.61	2.00

almost all drugs are available. UNIDO has certified that India possesses the technology for production of all essential drugs. But, in India, drugs do not occupy a large part of the market. According to the retail survey of Operation Research Group, total trade market of our country in 1985 was Rs. 1,777.58 crores. Of this, sales of essential drugs was Rs. 632.52 crores (53.12%) and sales of non-essential drugs was Rs. 552.05 crores (46.88%).

The above figures reveal that non-essential drugs like vitamin combination, tonics and nutrients occupy second position in terms of sales. Enzymes and sex hormones sold are comparable to the sale of anti T.B. drugs.

If highest selling individual drugs are considered, the figures are even more surprising. Out of the first 30 products, 11 are either non-essential or hazardous. They also include three items which are non-drugs.

It is therefore not surprising that major amounts of sales of the highest selling companies are made up by one or two non-essential or hazardous drugs. (See table below)

Company	Total retail Sale in 1984	Product	Sale in (Rs.) Crores	% of total yearly sale
Pfizer	40.65	Becosules	9.98	32.57
		Protinex	3.26	
Hoechst	33.16	Baralgin	6.76	36.40
		Novalgin	5.31	
Parke Davis	18.90	Benadryl	5.24	27.72
S.G. Chemicals	17.90	Phenyl & Oxy- phenbutazone Cp	4.12	23.02
Franco Indian	11.36	dexorange	6.15	54.00

Although the multinationals are supposed to manufacture basic bulk drugs, it has been repeatedly brought to notice that most of them have not

Over Production and Under Production of Drugs by Three Major Multinationals

Company	Unit	Licenced Capacity 1.4.83	Production 1984-85	Per cent Difference
Pfizer				
PAS & its salts	T	110.00	8.52	- 92.00
Protinex	T	110.00	279.30	+ 249.00
Glaxo				
Vitamin A	MMU	30.00	16.56	- 44.80
Betamethasone	Kgs	300.00	712.64	+ 137.55
E. Merck				
Vitamin-E	T	34.00	56.81	+ 67.09
Vitamin-K	T	4.30	Nil	- 100.00

only reduced the production of basic bulk drugs but they continue to over-produce non-essential drugs beyond the licenced capacity. Government's stand on such violation of licenced capacity has always been sympathetic to the industry and the drug consultative committee does not view such violations as an offence under law.

It needs a thorough analysis of production, licencing and distribution of drugs to understand the intricacies of increased production of non-essential drugs by the giant multinationals. An artificial demand of these non-essential drugs has been created by the multinationals for over one and a half decades. They have earned fabulous profits and they are desperate to maintain the market. When the Government asked them to reduce prices, they straightaway went to Courts and continued charging high prices with the help of Court injunctions. (See table below)

Product	Pack	Prices fixed by Govt. (Rs.)	Prices being charged (Rs.)	% Excess
<i>Pfizer</i>				
Becosules	20 's	6.13	8.85	44.37
	100 's	26.89	33.13	23.20
Protinex	115 gm	10.56	13.37	36.61
	225 gm	17.07	21.70	27.12
<i>Warner Hindustan</i>				
Nutrifil Liq.	750 ml	15.08	27.68	83.55
Waterbury's	250 ml	5.71	9.95	74.25
<i>Tonic</i>				
Listerine	85 ml	2.91	4.34	49.14
	400 ml	5.60	9.20	64.28
<i>Glaxo</i>				
Glucon-D	100 gm	2.15	4.19	95.00
	200 gm	3.95	7.64	93.00
	400 gm	7.12	14.46	103.00

Marketing Methods

In India over 45,000 formulations are sold, most of which are non-essential. This means that there should not be any real demand for these drugs. In reality, non-essential drugs continue to enjoy a large market demand. (See Table - I in Appendix)

The unique mechanism with which this demand of highly profitable non-essential drugs are sold is popularly known as high pressure marketing technique. In our country sufficient development had been made in marketing of drugs. An analysis by Shri M. Bhagat shows that 52 multinationals in 1978-79 spent only Rs. 1.56 crores in Research but Rs. 15.34 crores were spent for marketing. Most of the research houses have been

functioning for a long time but none of them could invent a single new medicine, excepting CIBA. A large part of their research is spent on product (formulation) development, market study and development of new sales promotion techniques.

Techniques Galore

Let us mention some of the unique marketing techniques of some of the pharmaceutical houses. One definite advantage that drug companies have is that their advertisement is mostly covert. It is not done, like for other commodities, openly in the common market place or through the mass media. This protects them from consumer reaction as they need not approach consumers directly. Their main concern are doctors, wholesalers and retail chemists. Their campaign is confined within a very narrow spectrum of the population. Therefore, the campaigns are cost effective and powerful.

Literature :

The drug companies, upto the sixties used to campaign mostly on the scientific development of medical science. They used handouts depicting complex molecular structures of medicines, complicated chemical process plants (although they did not establish any at that time in India), sophisticated analytical instruments etc. The attempt was simply to mystify pharmaceutical manufacturing and establish that only the multinationals can invent, implement and maintain such complicated systems of manufacturing. This mystification had a lasting effect. Even today, although the multinationals have not brought more new technologies than even the Small Scale Indian sectors, the prescribers have general illusion that drugs manufactured by multinationals are best. The report prepared by the Hathi Committee says — "Attractively got-up medical literature and international brand names of drugs appearing in advertisement in the foreign medical journals with which top consultants in the medical profession are acquainted, played their part in popularising drugs of the foreign companies".

Recent developments are even more disastarous. Distribution of handouts has been stopped by most of the drug companies. Folders or visual aids are now being used instead. They are not only colourful but some companies even use three dimensional effects and electronic gadgets as stunts. The folders or visual aids give a lot of opportunity to spread misinformation. After a particular promotional cycle is completed, these folders are collected by the companies and destroyed.

Advertisement :

Lay advertisements of drugs are very rare. Drug industry uses various professional journals of doctors and chemists. One of them is the 'Journal of Indian Medical Association'. A brief analysis of the advertisements in its August, 1985, issue is as follows :

There are 33 advertisements in this issue. Advertisement on the front cover page is of 'Vitazyme' which is a combination of vitamins and enzymes and that on the back cover page is of 'Benadryl', a cough syrup. Both are non-essential drugs.

There are advertisements for two baby foods — 'Lactogen' and 'Milk care'. Two nutrients, 'Horlicks' and 'Viva' are also advertised. For 'Viva', with a photograph of a person undergoing surgical operation, the following sentences are written — "Whatever the diagnosis Viva is good for your patients : Expectant mothers, Surgical patients, Convalescences; fever". Drugs having irrational combination like iodochloro-hydroxyquinoline with chloroquin is also advertised. Out of the 33 drugs advertised, 16 are either irrational or hazardous. This journal reaches 60,000 doctors every month!

Gifts and Bribes :

Gifts are another important factor used to boost sales. An extravaganza of varieties are found among the gifts. Various plastic gimmicks, toys, kitchen utensils, towels, ball point pens, thermosflasks, the list is endless. Special gifts are given to certain favoured doctors with their names imprinted.

Apart from these small bribes, direct bribing is widely resorted to, all over the World, by pharmaceutical multinationals. John Braithwhite in his 'Corporate Crime in Pharmaceutical Industry' has provided an elaborate account of bribing. Some examples :

- In Italy, a dozen drug manufacturers, including some American companies banded together to back an industry sponsored bill. The companies spent \$ 80,000 each, according to the source, with \$ 1 million to be donated to the Christian Democratic Party. The Government fell before the bill could be enacted.
(New York Times 31.3.76)
- Merck & Co. bribed a foreign Government \$ 2.3 million through its Swiss Subsidiary Merck Sharp & Dohme and recorded the amount as promotional expenses.
(U.S. Security and Exchange Commission)
- During the period 1971 to 1975, American Home Product spent \$ 3.4 million in bribing 41 countries to obtain action on necessary

Govt. clearance for granting approval. They also paid \$ 38,000 for an "Essentially Political Purpose".

- Parke Davis paid \$ 2.6 million in 14 countries to procure new product approvals.
- Pfizer bribed \$ 2,64,000 to employees of three foreign Governments. They also subscribed \$ 22,500 to a Foreign Trade Association to pay to different political parties of the particular country.
- Roche bribed \$ 14,000 to two Govt. officials in Kenya who purchased anti-bacterials and tranquilisers of the company amounting to 10 years need of the country.

Double Standards

According to the voluntary code of IFPMA (International Federation of Pharmaceutical Manufacturers' Association) "Information on pharmaceutical products should be accurate, fair and objective and presented in such a way as to conform not only to legal requirements, but also to ethical standards and to standards of good taste".

The constituents of IFPMA in India and under-developed countries consider that 'ethical standard' or 'standard of good taste' in these countries differ drastically from those of developed countries. Therefore, they maintain double standards. We mention a few such examples of double standards by multinationals in India.

1. The following drugs are not promoted by the multinationals in their own countries or in any developed country. Yet they are marketed in our country and have a sizeable market.

<i>Name of Drug</i>	<i>Company</i>	<i>Country of origin</i>	<i>Indications for which they are promoted</i>
Avil Expectorant	Hoechst	FRG	Cough Expectorant
Novalgin	Hoechst	FRG	Pain killer
Baralgan	Hoechst	FRG	Anti-spasmodic
Soventol	Boehringer Knoll	FRG	Cough Expectorant
Expectorant			
Piriton	Glaxo	U.K.	Cough Expectorant
Expectorant			
Periactin	MSD (Merind)	U.S.A.	Appetite Stimulant
Osto Calcium B ₁₂	Glaxo	U.K.	Growth Tonic
Ganrilon	S.G. Chemicals	Swiss	Pain killer
Suganril	S.G. Chemicals	Swiss	Anti inflammatory
Esgipyrin	S.G. Chemicals	Swiss	Anti inflammatory

2. *Osto Calcium B₁₂*

Osto Calcium B₁₂ is a combination of Calcium Phosphate, Vitamin-D and Vitamin B₁₂ marketed by Glaxo Laboratories in India. This formulation is not marketed in any developed country including the parent country of the company. In text books Vitamins B₁₂ is indicated in one rare disease 'Pernicious anaemia'. Human Liver is the largest store for Vitamin B₁₂ which can provide Vitamin B₁₂ atleast for five years without exogenous help. Most important, Vitamin B₁₂ has little role in pernicious anaemia if taken orally. Glaxo Laboratory promotes *Osto Calcium B₁₂* with the following slogans :

- "Growing children, expectant mothers, and nursing mothers need calcium with phosphorus. During growth years it is essential".
- "In addition Ostocalcium B₁₂ is enriched with Vitamin B₁₂ for *Growth & Appetite*".

To give a scientific colour, the company promotes this drug with reference from a scientific journal — "But doctor you know Ostocalcium B₁₂ Syrup is converted into a ready-to-absorb solution by Gastric Hydrochloric Acid (Hcl). Here is a reference from April 1973 issue of *Lancet* Page 820-821. Therefore, Ostocalcium B₁₂ syrup is effectively absorbed".

The quotation is a total fabrication as the April 1973 issue of *Lancet* does not run to 820 pages!

3. *Chloramphenicol and Streptomycin Combination*

In developed countries Chloramphenicol is preserved for treating Enteric diseases (Typhoid). In the underdeveloped countries it is used for all types of infections. Most dangerous is its use in diarrhoea. This combination is widely used for treating diarrhoea, which is a major killer disease in the underdeveloped countries. No multinational company markets this combination drug in developed countries. In one of the literatures of promotion for this product the following quotation was made with the 'logo' of UNICEF. "Diarrhoea is one of the two major pediatric diseases". Thus even UNICEF is used as a marketable commodity!

4. *Periactin*

Cyproheptadin is an anti allergic drug. Increased appetite is one of the side effects of this drug. This drug is promoted for this side-effect. The use of appetite stimulants can mask the real disease which is causing loss of weight and loss of appetite. In some of the visual aids of the drug the company says — "Periactin helps revitalise appetite; encourages greater food intake; increases body weight through appetite stimulation. The drug is superior as a stimulant of appetite and weight gain to the medication we used previously (Multivitamins, Sedatives and Anabolic steroids)"

5. *Artiran Story*

One of the most striking incidence of manipulation of information has been in the promotion of Artiran by S.C. Chemicals (a subsidiary of CIBA Geigy). Artiran, brand name of Sulphinpyrazone, was promoted by S.G. Chemicals with the help of a four page folder.

On page 2 of the folder, incidence of myocardial infraction was given and then a graph is shown of the study on Artiran Reinfraction Trial Research Group (ART Study) published in the *New England Journal of Medicine*, 302 : 250, January, 1980. It is claimed in the folder that Artiran "had caused an astonishing 74 per cent reduction in sudden death during the critical period of two to seven months after infraction".

Whereas the editorial of *New England Journal of Medicine* issue 303 : pg. 1476-7, Dec. 80, says under the caption 'SULPHINPYRAZONE AFTER MYOCARDIAL INFRACTION : NO DECISION YET' — "According to a new release from the Department of Health, Education, & Welfare, a view of case records submitted by the drug company showed that many deaths had been misclassified and that others had been inappropriately excluded from the study ... the FDA said there was no statistically significant difference. Regardless of what emerges from further review of these data, we will need more clinical trials before we can be sure of the value of sulphinpyrazone ..."

Lancet pg. 306-7, August 1980, wrote on ART :

"The reduction in sudden deaths, said FDA, had been exaggerated" "The issue, moreover goes beyond allegedly faulty research design. The reason for these doubts is that CIBA-Geigy, which had a stake in the outcome, not only paid the bills (around four million dollars) but also was deeply involved in the daily processing and collection of data before turning over the information to an independent policy committee".

On page 3 of the folder used by the company it is mentioned "Artiran is the only anti-platelet drug with documented efficacy superior to Aspirin". It is illustrated by a graph which refers to 'Aspirin Myocardial Infraction Study Research Group' — *JAMA* 243, 661-669, 1980. This is known as AMIS Study. It was revealed that the graph as published in this literature is non-existent in the original paper. In fact the graph has been devised by M/s. SG Chemicals. In reality the conclusion of the study said "Aspirin is not recommended for routine use for patients who have survived Myocardial Infraction". There is no mention of Sulphinpyrazone at all.

What is needed

The aggressive and high pressure sales techniques of the multinationals have been criticised all over the world. The WHO conference of Experts

on the Rational use of Drugs, held at Nairobi 25-29 November, 1985, commented :

"All experts spoke in favour of the application of ethical criteria in drug promotion. It was generally felt that the pharmaceutical industry has major responsibility for campaigning with established criteria and avoiding different standards in different countries".

We are yet to know of any response from our Government, which is incapable even of implementing its own decision on banning of hazardous drugs. In this area the following measures are needed urgently :

1. Rational Drug Therapy to be included in the medical curriculum. There should be prescription audit system and compulsory refresher courses for prescribers to wipe out any lack of knowledge of therapeutics and Pharmacology. The basic training must aim at developing in the student a critical attitude that will enable him to judge rationally the flood of information to which he is subjected.
2. A periodical information bulletin has to be published for reference work which is to be distributed free of cost to the prescribers (like British National Formulary).
3. No drug company should be allowed to publish/circulate any promotional literature and/or its product's advertisement without being screened by a National Authority.
4. A levy should be charged on all large companies on their total expenses on sales promotion for research and drug development.
5. All trials have to be monitored by the National Authority. Trials should be performed under strict control and processing and collection of data shall be conducted by an independent policy committee.
6. No drug company should be allowed to sponsor any seminar, conference, etc. of doctors, chemists, etc.
7. No drug company should be allowed to give samples, gifts, etc., to the prescribers. Samples can be given for a new drug on request from the prescribers upto a particular period under the supervision of the National Authority.

Table - 1

Growth of Highest Selling Non-Essential Drugs

Rank	Product	Company	(Rupees in crores)		
			Retail sale in 1979	Retail sale in 1985	Growth (per cent)
2	Becosules	Pfizer	6.75	11.83	75.26
5	Dexorange	Franco Indian	2.75	7.91	187.64
7	Baralgan	Hoechst	3.86	7.74	100.52
9	Vicks Vaporub	Richardson Hindustan	2.93	6.84	133.45
10	Novalgin	Hoechst	2.32	6.37	174.14
13	Liv-52	Himalaya Drugs	3.26	6.36	9.09
16	Betnovate-N	Glaxo	2.68	5.79	116.04
17	Neurobion	E. Merck	2.45	5.68	131.83
23	Benadryl	Parke Davis	3.04	4.90	61.18
28	Glucon-D	Glaxo	2.61	4.10	57.09
29	Iodex	S.K & F	1.26	4.08	223.80

Table - 2

Growth of Alcohol Based Tonics

Product	Company	1979 (sales)	1974 (sales)	Growth (percent)
Santiveni	Sandoz	1.83	3.05	66.67
Neogadine	Raptakos Brett	1.46	3.05	108.90
Bayers' Tonic	Bayer	1.45	2.54	74.17
B. G. Phosh	Merind (MSD)	1.40	2.06	47.14
Waterbury's	Warner	1.40	2.15	53.57
Phosphomin	Sarabhai	1.19	3.00	68.06

N.B. These six companies enjoy 49% of the total tonic market

Table -3

Growth of Protein Supplements

Product	Company	(Sales in crores of Rupees)		
		Retail sales in 1979	Retail sale in 184	Retail Growth (per cent)
Protinex	Pfizer	2.40	3.26	35.85
Complan	Glaxo	0.85	2.19	257.64
Protinules	Alembic	1.64	1.62	(-) 1.23

These three companies account for 52% of the total market in this group

Table -4

Growth of Cough Syrups

Product	Company	Retail		
		sale in 1979	sale in 1984	Growth (per cent)
Benadryl	Parke Davis	3.03	5.18	70.95
Phensidyl	May & Baker	1.59	2.91	83.01
Corex	Pfizer	1.20	2.71	125.83
Coscopin	Biological E	1.07	2.12	98.13
Piriton	Glaxo	0.17	1.78	947.05

These five companies share 52.9% of the total cough preparation market.

Table -5

Types of drugs promoted by the Top Three Companies in 1984-85

Company	Drug	Products	Types of products
Pfizer	Terramycin	Oxytetracycline	Essential
	Combantrin	Pyrental	Essential
		Palmoale	
	Deltacortil	Steroid	Essential
	Becosules	B-Complex	Non-essential & irrational
	Dumasules	Haematinic	Essential but Irrational formation
Glaxo	Corex	Cough Syrup	Non-essential
	Protinex	Protien supplement	Non essential and non-drug
	Almacarb	Antacid	Essential but irrational
	Cilin	Vitamin-C	Essential
	Betnovate	Steroids	Essential
	Ostocalcium	Combination of Vitamin-D	Non-essential
		Calcium and Vitamin B	
	Piriton	Cough Expectorant	Non-essential
	Cobadex	Combination of B1, B6, B12	Non-essential
	Haliborange	Vitamin A, D, C & orange juice	Non-essential
Hoechst	Albercillin	Ampicillin	Essential
	Servoprim	Cortimoxazola	Essential
	Lasix	Diuretic	Essential
	Baralgan	Anti-spasmodic	Hazardous
	Novalgin	Analgin	Hazardous
	Vitahext	Tonic	Non essential
	Avil	Cough	Non essential
	Expectorant	Expectorant	
	Festal	Digestive Enzyme	Non essential

Implications of Import Policy on Intermediates and Bulk Drugs Production

*Sandhya Gautam**

It has been observed that the production of a Bulk drug from a particular stage is influenced by factors that are controlled by government policies of pricing, imports etc. Undoubtedly a product grows fast when the raw materials required for its production are indigenously available at a reasonable price, for they constitute the major cost element in the overall cost structure of the drug. The beginning of the industry was marked by mere processing of formulations and since then industry has grown sizeably due to the favourable policies pertaining to production, imports sectoral reservations etc. The government in its endeavour to achieve the objective of self reliance asked drug companies to produce bulk drugs from basic stage. In this process, we developed the capability to produce almost every drug but sufficiency was not achieved, due to varied reasons. This brought us to a situation where demands are met by indigenous production as well as imports.

In this paper, an attempt has been made to study policies pertaining to Bulk drug production in terms of raw material availability. In this context, impact of import policies on production of bulk drug, its cost and technological capabilities thus acquired have been studied.

A Growth Profile

Looking at the profile of the drug industry and its growth we find that investment in the industry has increased by 20 folds, considering 1952-53 as the base year. The bulk drug activity increased 13 times measured from 1963-64. The formulation activity increased impressively by 50 folds with 1952-53 as the base year. Dependence on imports in this period, have gone up by 10 times.¹

The imports have taken place mainly for bulk drugs, formulations, raw materials and intermediates. It will be seen from Table I that nearly 75-80% of the value of imports is accounted for by bulk drugs. Formulation

imports are negligible. Nearly 20% of the value of imports is for raw materials and intermediates, which can be interpreted in two ways :-

1. Our import policy allowed lower duties on bulk drugs and higher on intermediates so that the preference for importing bulk drugs had an edge over indigenous production.
2. Import of raw materials and intermediates in sizeable amounts consistently meant that backward integration did not succeed much and we could not really strengthen our organic chemical base.

Import and its implications

The emphasis of import policy has been on providing easy access to imports essential for maximising production and at the same time for the objective of self reliance and safeguarding the interests of the people. To ensure this, several steps were taken by the government to restrict, canalise or allow drugs to be imported by actual users (industrial) on Open General License (O.G.L.), which are not produced indigenously or whose total production is inadequate to meet the demand.

Our continued dependence on Imports is due to unavailability of technology, uneconomical plant sizes as well as substantially liberalised import policy. Now regarding uneconomical plant sizes, plant capacities are distributed to a number of licencees due to good reasons. These small capacities hamper economies of scale and more so in comparison to other world size plants.

As far as availability of technology for the production of drugs is concerned, it is natural to import drugs when the technology is not available indigenously. Once capability to produce them is developed indigenously, then consistent imports can only result in other implications for the Drug Industry.

Implications of undesirable and not so necessary imports are, foreign exchange drain and underutilization of our capabilities. Apart from genuine foreign exchange drain, we have been draining it by paying more prices for imported drugs and raw materials. The issue has been raised time and again and there is no dearth of instances where products have been overpriced.

In order to find out the extent of overpricing by various companies from different or same source, a small exercise has been done here to calculate overpricing for recent imports. This has been done for drugs and intermediates that are totally imported and those which are produced indigenously as well as imported.

This is based on weekly Import statistics of Bombay port between March 1985 - Feb. 1986. The costs mentioned are landed costs of imports. The price variance is calculated on the basis of maximum and minimum

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price paid by firms for the same imported drug and intermediate. It has been calculated separately, for bulk drugs and Raw Materials/Intermediates. For this a purposive sample of 28 bulk drugs and 15 Raw Materials/Intermediate was analysed. Out of 28 bulk drugs, the price variance was observed for 19 drugs whereas in case of Raw Materials it was observed in 7 cases out of 15.

Totally Imported drugs : Table 2 shows the price variance for drugs that are totally imported. During the aforementioned period, costs of imports for various companies have been taken into consideration to list out maximum and minimum costs paid for the import. As is revealed by the sectoral analysis of the companies involved in imports, Foreign Sector paid more than its counterpart in 3 cases out of 10. Information is not available in one case about the sector. Small scale sector paid more in 6 cases and less than its counterpart in 7 cases. Foreign and Indian Sectors paid less than their counterparts in one case each.

The point which needs attention is that the variance has been observed not only when the imports are from the same country but even during the same period e.g. in case of Dipyrindamol, the same company paid 300% less than what it had paid for imports only a month back and another company paid 600% more than what the former company had paid around more or less the same period. It can be seen from the Table that the difference between maximum and minimum price paid varied from 1 to 13 times.

Drugs that are both produced and imported : Table 3 shows this price variance for drugs that are imported, as well as indigenously produced. Here analysis reveals that Foreign Sector paid more in 4 and less than its counterpart in 1 case. Small Scale Sector paid more in 4 cases and less in 8 cases. Indian Sector paid more in 1 case. Here the maximum variance was observed to the tune of 8 folds.

The main point which needs to be taken note of is that these price variations to the tune of thousands of Rupees have been calculated for 1 Kg. of drug. This, when estimated for huge quantities of drugs that are imported, will run to Crores of Rupees. It has not happened only when the source of import is different or importing sectors are different but even when the source as well as importing sectors are the same.

This issue has been discussed to show that when imports are not properly regulated and even in those cases where the capability to produce them exists in the country, how taxing they can prove to be.

Raw materials and intermediates : Overpricing of Raw Materials has been exemplified in Table 4 for period between 1970-73.² It is seen that Raw Materials have been overpriced by even more than 300 percent.

Similarly, variance in landed costs of imports in case of raw materials and intermediates can be seen in Table 5. It may be noted that this

variation for raw materials may not appear substantial when calculated for the small unit. This, however becomes significant when calculated for the large quantities that are imported. Here foreign sector was found to pay more in 2 cases, Indian in 1 case. Small scale sector was found to pay more in 4 cases and less in 6.

Anomalies in Custom Duties

The industry has suffered due to irrational and anomalous duty structure. The custom's duty on bulk drugs is 100% whereas it is 135% in case of intermediates with few bulk drugs as well as intermediates exempted from duty. This has been done with a view to promote self-reliance and to encourage production from the basic stage.

Here one finds the situation entwined in a dichotomy which relates to : —

1. Government's role in providing essential and life saving drugs at cheaper price, when they are not produced in abundant quantities or not produced at all in the country. This is done by doing away with duties.
2. In a situation where generally cost of indigenous production is high due to high input costs, allowing imports of bulk drugs at less duty and asking manufacturers to produce them from the basic stage does not encourage self-reliance.

Another problem relating to duty structure of intermediates and raw materials is that it is difficult to define drug intermediates because a number of chemicals used for drug manufacture are also used in dyes, pesticides etc. It can lead to formulation of drugs by non-drug formulators at cheaper costs.

In order to understand the complexity of the situation and impact of the custom's duty on bulk drug production, few cases have been put forth which are :

- i. Rifampicin has been imported in large quantities in our country and we have been merely doing the formulation by importing Rifampicin bulk. The Intermediates used are, Rifampicin 8,3, Formyl Rifampicin SV and 1 Amino 4 Methyl piperazine. Earlier the duty on these 3 chemicals was 105%. An Indian company has developed the technology in collaboration with a national laboratory from the basic stage. The duty on intermediates was totally exempted in Feb. 1985.
- ii. A recent change in duties on TIOC and 6APA used in the production of Erythromycin and Ampicillin has shown an opposing trend. The duty on TIOC has been raised from 25% to 140% ad valorem and in case of 6APA from 25% to 100% ad

valorem. This has been done by the Government to encourage indigenous production as about a dozen companies have been licenced to produce these drugs. This is a welcome step but this has also hit the small scale manufacturers who were merely involved in formulations. Similar is the case with L base used for the production of Chloramphenicol.

- iii. Ethoxy methylene diethyl malonate used in the production of Chloroquin is exclusively imported at a concessional duty of 25% ad valorem. National Chemical Laboratory has developed a process which makes use of other raw material and the process is novel.³ This technological superiority has been offset by the duty advantage.
- iv. An example of duty anomaly for raw materials and intermediates can be seen in case of Trimethoprim. Its intermediate 3, 4, 5 Trimethoxy benzaldehyde enjoys concessional duty of 110% whereas raw materials required for its manufacture attract a duty of 134%. How can we achieve backward integration in such cases where raw materials are not produced in the Country?
- v. Technological capabilities exist in the Country to produce L-Dopa. It was imported to the tune of 44 lakhs last year at nil duty. Vanillin, one of the raw materials for the manufacture has a duty of 135%.
- vi. Digoxin is being produced indigenously by the organised sector. Digitalis leaves required for the production are grown in India but they have also been exempted from duty. Now, with the exemption of duty, the companies may import in large quantities.
- vii. Likewise, we are in a position to manufacture Sulphadiazine and corticosteroids but their import is allowed freely at a duty of 100% while duty on intermediates is 135%.

At the same time it cannot be denied that easy indigenous availability of raw materials has undoubtedly facilitated the growth of many drugs viz Sulphamethoxazole, PAS, Thiacezone etc., whereas growth is definitely hampered when raw materials and intermediates are not available indigenously.

Now looking at the strength of our organic chemical base it has been seen that out of 42 intermediates used in the production of bulk drugs, we have no capacities for 19, partial capacities for 10 and full capacities for 10.⁴ The situation with regard to a few drugs like INH, Ethambutol, Chloroquin and L Dopa can be seen from Table 6. Thus, even in cases like Gamma Picoline, where we have the capacity, we see duty reduction from 135 to 45%.

This has been discussed here to make the point that since we

lacked somewhere in building our chemical base (reasons could be many), the alternative which is left to make them available cheaply is by way of reducing duty on them when they are not available indigenously and then restricting imports once capability is developed.

Conclusion

What we have witnessed in the early stages of the development of drug industry was a policy rather restrictive in terms of imports which brought in its wake a certain degree of self reliance. What we witness today is a policy which is liberal in its nature. However, a peculiar situation exists today where the drug is produced indigenously but not sufficiently. The balance is being made up by imports which are cheaper as compared to indigenous costs of production. It has created a situation where government's intervention is inevitable and highly desirable. In terms of our objectives for consistent growth, self reliance is one area where a consensus has always been there. What is required is a clear cut priority of objectives and planning accordingly. However, the following points need to be taken care of :—

1. As we have seen a sizeable difference of imports between bulk drugs and intermediates which has been attributed to anomalous duty structure, this should be carefully analysed. It should be such that it encourages the production of bulk drugs from basic stage. Lower duties on finished products will make producers import the final product. Thus duty structure should be such that it gradually decreases while going to basic stage i.e. a relative duty structure is to be preferred. It should be an incentive for a producer to go basic rather than a disincentive. Otherwise in the situation where we stand today, which is of less or no duty on final products, Formulators will not prefer to produce from basic stage. Import and custom duty structure should be such so as to encourage backward integration.
2. Another aspect of it is that we should seriously think of strengthening our organic chemical base. However, it is not necessary to produce everything from the basic stage but an effort should be made to harness our capabilities. As we have adopted the policy of backward integration it may not be desirable in certain cases to go basic due to smaller demand or economies of scale.
3. Once we have the capacity available in our Country for the drug, intermediate duties on that particular product should be enhanced so as to encourage indigenous production and discourage imports. We should ensure creation of enough capacities. There is no dearth of instances where we have developed and pioneered the technology

but imports have continued. In case of uneconomical capacities, one way of helping the manufacturer could be by way of reducing taxes on indigenous raw materials, intermediates and finished products.

4. As we have seen so much of price variance in terms of input costs amongst various companies who are importing the same product at different costs, an answer to this problem is canalisation *but not the way it is operating at present*. Functioning of canalising agencies need improvements. Drugs and intermediates should be available only through the canalising agency. This will also take care of transfer pricing. Moreover it will ensure that the cost of imported product will be same for importers.

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4. *op. cit.*

Table 1

Break Up of Import Figures of Drugs and Pharmaceuticals from 1980-84 (in crores)

	1980-81		1981-82		1982-83		1983-84	
	Value	% value of total imports	Value	% value of total imports	Value	% value of total imports	Value	% value of total imports
Bulk Drugs	95	80	87	77.12	105	76.77	115	77.45
Formulations	1	.83	9	7.98	1	0.73	5	3.37
Intermediates,	22	18.33	15	13.30	29	21.20	25	16.84
Chemicals & solvents								
Mechanical	.04	.03	.26	0.23	.43	0.31	2	1.35
Contraceptives								
Total	120.03	100.00	112.81	100.00	136.77	100.00	148.48	100.00

Source : Ministry of Chemicals and Fertilizers.

Table 2
Comparative Costs of Drugs Imported by Various Companies
For Drugs That Are Totally Imported

Name of Drug	Countries from where imported	Importing Sector/ country from which imported	Period during which Imported	Landed Cost of imports in Rs./kg.	Price Variance (Ratio)
1. Cephalixin	Italy, UK	S.S. UK	27.1. - 3.1.86	2,276	
2. Verapamil	Italy, W.Ger. Finland	S.S. UK	6.9. - 13.9.85	175	2101 (1:13)
3. Norgestrol	Netherlands	W. Germany*	22.11 - 29.11.85	2,653	
4. Dipyridamol	W. Germany	S.S. Italy	1.11 - 7.11.85	1,222	1431 (1:2.45)
5. Cimetidine	China, Germany	Foreign W.G.	10.1 - 17.1.86	2,13,044	
6. Naproxen	Hungary, Italy	Foreign W.G.	6.9. - 13.9.85	86,870	126174 (1:2.45)
7. Cloxacillin	Germany	Foreign Germany	6.12 - 13.12.86	2,466	
8. Rifampicin (OGL)	Italy	S.S. China	10.10 - 18.10.86	394	2072 (1:6.26)
9. Neomycin	France	S.S. Italy	25.6 - 4.7.85	661	605 (1:1.80)
10. Pyrazinamide (OGL)	Singapore	S.S. W.G.	27.12 - 3.1.86	56	
	Italy, Bulgaria, Korea, Germany	S.S. Italy	6.12 - 13.12.85	1604	
	USA, Hungary	S.S. Italy	28.3 - 30.3.85	1440	164 (1:1.11)
	France	S.S. Singapore	25.5 - 31.5.85	1588	
	Italy	S.S. Italy	21.3 - 27.3.85	856	732 (1:1.85)
	Korea, Germany	S.S. Bulgaria, Indian	27.1 - 31.1.86	3837	
	USA, Hungary	Korea	1.3 - 6.3.86	2417	1420 (1:1.59)
	France	Foreign, France	13.3 - 20.3.86	1788	
	Korea, Italy	Indian, Hungary	13.5 - 17.5.85	823	965 (1:2.17)
		S.S. Italy	20.4 - 26.4.85	1448	
		S.S. Korea	2.8 - 9.8.85	642	806 1:2.25

Source : 1. Compilation from weekly import statistics of "Chemical Weekly".
2. Refers to imports taken place through Bombay port between March 1985 and Feb 1986.

S.S. = Small Scale

* Not available

Table 3
Comparative Costs of Drugs Imported by Various Companies
For Drugs That Are Both Produced and Imported

Name of Drug	Countries from where Imported	Importing Sector/ country from which imported	Period during which imported	Landed Cost of Imports in Rs. / kg.	Price Variance (Ratio)
1. Betamethasone	Italy USA Portugal	Foreign Portugal S.S. Italy	19.9 - 25.9.85 10.10 - 18.10.85	63,670 34,332	29,338 (1:1.85)
2. Hydrocorti-sone (OGL)	France, USA Germany, Spain	Foreign Spain S.S. Italy	1.11 - 7.11.85 6.9 - 13.9.85	8,109 3,838	4,271 (1:2.11)
3. Prednisolone (OGL)	France, Hungary W. Germany	Foreign, France S.S. Hungary	10.2 - 14.2.86 14.9 - 47.9.85	14,508 9,113	5,389 (1:1.59)
4. Dexamethasone Sodium Phosphate (OGL)	Italy	Foreign, Holland S.S. Italy	10.10 - 18.10.85 6.12 - 13.12.85	38,677 17,790	20,887 (1:2.17)
5. Mebandazole (OGL)	Belgium	S.S. Belgium	14.9 - 17.9.85	1278	504 (1:1.7)
6. Ranitidine	Italy, Spain France China	S.S. Belgium S.S. Italy S.S. Spain S.S. China	15.7 - 18.7.85 20.1 - 24.1.86 10.1 - 12.17.86 28.3 - 30.3.85	774 2,247 1,752 921	495 (1:1.28)
7. Ephedrine (OGL)	W. Germany U.K. China	S.S. China Indian, UK	15.7 - 18.7.85 15.7 - 18.7.85	306 3,729	615 (1:3)
8. Pseudoephedrine	Finland, Italy, W. Germany	Foreign, W.G. S.S. Finland S.S. Italy	1.11 - 7.11.85 21.3 - 27.3.85 6.9 - 13.9.85	481 4,119 3,368	3,248 (1:7.75)
9. Salbutamol (OGL)					751 (1:1.22)

Source : 1. Compiled from Weekly import Statistics of "Chemical Weekly".
2. Refers to imports taken place through Bombay port between March 1985 Feb. 1986
S.S. = Small Scale

Table 4
Over-pricing of Certain Raw Materials in Drug Industry

Raw Material	Per Unit Price paid by Domestic Firms	Per Unit Price paid by Firms with MNC Connections	Extent of Over-pricing (%)
Paranitro-toluene	0.0375	0.0537	141
Sodium Nitrate	0.0116	0.0380	328
Dinitrochlorobenzene	0.0185	0.0321	173
Orthotoluidine	0.0531	0.1321	249
Bromine	0.0876	0.1086	124
Paranitrolune	0.0375	0.1018	274

Source : Subramanian & Pillai; "Implications of Technology Transfer : Export Led Growth Strategy", Economic and Political Weekly, 1976.

Table 6
Intermediates/Chemicals Required for Production of A Few Bulk Drugs

Name of Chemical	Estimated Requirements 1984-85	Registered Installed Capacity
Gamma Picoline	700	Partial Capacity 500 MT created
Hydrazine Hydrate	360	Full Capacity
DL2 Amino butanol	600	No Capacity
Ethylene diamine	700	No Capacity
m-Chloro aniline	200	Adequate
Diethyl Malonate	320	No Capacity created
Novaldiamine	200	No Capacity created
Vanillin	60	No Capacity

Source : Gharpure, Y. H.; Drugs and Pharmaceuticals : A Critical Study, Chemical Weekly Annual 1985, pp. 76b.

Table 5
Comparative Costs of Imported Raw Materials and Intermediates

Name of Raw Material/ Intermediates	Countries from where Imported	Importing Sector/ Country from which imported	Period during which imported	Landed Cost of Imports in Rs./ Kg.	Price Variance (Ratio)
1. Mannitol	France Australia Brazil, China West Germany USA	S.S. France S.S. Australia	23.8 - 30.8.85 10.2 - 14.2.86	648 16	632 (1:40)
2. Novaldiamine		Indian, W. Germany S.S. W. Germany	20.12 - 26.12.85 2.9 - 3.9.85	168 15	153 (1:11)
3. Alpha Naphthol	Japan Korea W. Germany	S.S. Japan S.S. Germany	20.12 - 26.12.85 20.12 - 26.12.85	65 46	12 (1:1.14)
4. Phenol	Japan W. Germany U.S.A.	Foreign W.G. S.S. Japan S.S. USA	10.1 - 17.1.86 12.8 - 16.8.85	15 8	7 (1:2)
5. Vanillin	France Japan USA	S.S. France S.S. USA	10.9 - 18.9.85 13.3 - 20.3.85	150 126	24 (1:1.2)
6. Gamma Picoline	W. Germany Japan	S.S. Japan Foreign W.G.	14.11 - 22.11.85 27.12 - 3.1.86	45 37	8 (1:1.2)
7. Guanidine Nitrate	Japan	Public W.G.	10.2 - 14.2.86 2.5 - 10.5.85	23 14	9 (1:1.64)

Source: 1. Compiled from weekly import statistics of "Chemical Weekly"

2. Refers to imports taken place through Bombay port between March 1985 to March 1986.

S.S.=Small Scale

Licensing Policies and Growth of Drug TNCs in India

Sudip Chaudhuri*

The TNCs and their supporters have demanded complete delicensing in the drug industry. They argue that the present policy of reserving a specified list of drugs for the indigenous sectors, i.e., the policy of preventing the TNCs from manufacturing them, have resulted in shortages necessitating larger imports.¹ That the present situation is unsatisfactory, so far as the basic question of tackling the health needs of the people is concerned, is generally agreed. But the present policy of "discrimination" is of recent origin. It can be traced back essentially to the enactment of the Foreign Exchange Regulation Act (FERA) in 1973.² We will discuss in the present paper : (a) Before FERA what was the performance of the TNCs in manufacturing drugs in India and reducing imports (b) To what extent the claim of the drug TNCs, that the present policy is adversely affecting their growth, is justified. By drug TNCs we mean all those firms operating in the drug industry in India, which are solely controlled by TNCs from developed countries. This category includes not only those firms which are solely owned by them or where they own more than 50 per cent of the equity shares. A firm even with a block of foreign equity less than 50 per cent is considered as solely controlled by TNCs, if, e.g., there is direct or indirect evidence that the remaining Indian shares are widely dispersed. We have identified 63 firms as TNCs. They comprise both FERA companies (foreign equity more than 40 per cent) e.g., Burroughs Wellcome & Co., Roche Products etc., and non-FERA companies, e.g., Boehringer Knoll, German Remedies etc.³

Before FERA

Drug manufacturing by the TNCs in India is essentially a post-Independence phenomenon. They did not take any initiative to manufacture, though no constraints were imposed on their operations during

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the colonial period. Their products were available through imports. A number of them did set up separate companies or branches in India. But the purpose was to look after the distribution and sales of the imported products. Thus, Parke Davis' representative came to India in 1899 and a branch was opened in 1907.⁴ Similarly, Burroughs Wellcome set up a branch in 1912. Glaxo (the U.K. Company was then known as Joseph Nathan & Co.) took over in 1926 an agency house, H.J. Foster & Co. (incorporated in India in 1924), which had been marketing Glaxo's baby food. While Ciba's synthetic dyestuffs were available in India since 1890s and pharmaceutical products since 1925, a company was set up in India in 1928 with a separate pharmaceutical division in 1941. Among the TNCs which exported drugs to India through local firms or licensed importers were Cyanamid (then known as Lederle), Sandoz, Merck & Co. etc. J. L. Morison, Son & Jones was an important agency house which looked after the imports of a number of companies, including those of Sandoz.

After India's independence, naturally some policy changes were expected. The Prime Minister announced in 1949 that new foreign capital would be encouraged "on terms and conditions that are mutually advantageous" and existing foreign interest would be provided "national treatment", i.e., there would not be any discrimination between foreign and Indian enterprises.⁵ The notion of what is "mutually advantageous" has changed over time and has varied from industry to industry. The government was, at least, initially favourably disposed towards the new drug TNCs. As the Industrial Adviser (Drugs & Pharmaceuticals) of the Government of India pointed out :

"It was felt from the beginning that an industry of this nature could grow only with the fullest collaboration, both scientific and technological, of countries that had already achieved a high degree of proficiency in the field of pharmaceutical research and manufacture".⁶

The Organisation of Pharmaceutical Producers of India admitted that "several international companies were invited, encouraged and assisted by the Government" ⁷ The Prime Minister's assurance about non-discrimination applied also to the foreign enterprises set up after 1949.⁸ Obviously, a firm which is new today becomes an "existing" one tomorrow. Let us now see how the TNCs responded to such favourable policies.

Post-Independence Scenario

In the post-Independence period, companies such as Glaxo, Boots, Burroughs Wellcome, Parke Davis, etc., which were already functioning in India as importers and distributors, began manufacturing. A number of

companies, e.g., Hoechst, Roche, Bayer, Organon were newly established (cols. (1) and (2) of Table 1). All the TNCs however did not start manufacturing immediately after independence. Information on the year of commencement of formulation production is available for 29 major companies, together accounting for about 88 per cent of the total sales of the TNCs in 1978.⁹ Among the early ones, May & Baker set up its factory in 1948 though it had been engaged in packaging and manufacturing of a few formulations on a modest scale since 1943. As col. (3) of Table 1 shows, Glaxo, Boots and probably Ciba Geigy (then Ciba) began formulating in the late 1940s. Cynamid, Parke Davis, Hoechst, Merck Sharp & Dohme and at most seven others followed suit in the 1950s. It was not before 1960s that at least 14 companies (at least 3 of them in 1970s) set up their own formulation plants. Among the late starters in India are such giant TNCs as E. Merck, Richardson Merrell (Richardson Hindusthan in India), Bayer, Warner Lambert (Warner Hindusthan in India), Akzo (Organon in India) and Searle (Table 1).

The import trading activities of the TNCs continued even in the post-independence period as a prelude to their own manufacturing arrangements. Sandoz, e.g. which was incorporated in India in 1947, restricted its activities solely to selling imported products till 1958 when steps were taken to instal a plant. Dumex¹⁰ was set up in 1950 to deal with Danish imports which were previously looked after by another company. Pfizer, which had been exporting its formulations to India, entered the pharmaceutical industry in India by acquiring Dumex in 1958 which, meanwhile, had commenced manufacturing. German Remedies, too, was established in India in 1949 to distribute imported products. Its shareholders include five West German companies — C. H. Boehringer Sohn, Chemiewerk HOMBURG, Nordmark-Werke, Schering, and Bauer & Cie (WULFING). The name of the company, in fact, was changed to German Remedies & Trading Co. in 1952 to emphasize its trading activities. Its manufacturing activities started in early 1960s.

Bulk Drug Production

Bulk drug production by the TNCs lagged behind formulation production, both temporally and in magnitude. Information on the year of commencement of bulk drug production is available with us for all the TNCs which started bulk drug production by the late 1970s except two smaller units, Ethnor and Indian Schering. Table 1 shows that before the late 1950s, Rallis and May & Baker alone were engaged in bulk drugs production. The companies such as Glaxo, Boots, Parke Davis, Cyanamid etc. which had opened formulation plants were then merely processing imported bulk drugs. During the Second World War, Teddington Chemical

Factory (which merged with Rallis in 1961-62) took up the manufacture of Liver extract. In 1950 a plant was set up by May & Baker to manufacture sulphur drugs (Sulphapyridine, sulphadiazine etc). Prior to it, the manufacture of L-Ephedrine Hcl. was started in 1948, but was later discontinued.

The bulk drug production by the TNCs on the whole began effectively in the late 1950s and really took off in the 1960s. Production of such important categories of bulk drugs as antibiotics (Tetracycline, Oxytetracycline, Chloramphenicol etc), cortico steroids (Prednisolone, Dexamethasone, Betamethasone etc), anti-malarials (Amodiaquin, Chloroquin Phosphate), antidiabetics (Insulin, Tolbutamide, Chlorpropamide), anti-Leprotic (Dapsone) etc. were all initiated by the TNCs in the early 1960s. At least 13 companies (Burroughs Wellcome, Cyanamid, Parke Davis, Bayer etc) entered the field for the first time in the 1960s, compared to at most nine companies (e.g. Glaxo, Hoechst, Pfizer) in the late 1950s (col. (4) of Table 1). But the companies which began manufacturing bulk drugs in the late 1950s, did so with a few bulk drugs only; they actually diversified into a wider range later. Thus Merck Sharp & Dohme and Hoechst initiated bulk drug production in 1959 with a single item each (Vitamin B₁₂ and Procaine Hcl., respectively), while Pfizer was producing two and Glaxo four bulk drugs in the late 1950s.

Organon, E. Merck, Uni-Sankyo and Reckitt & Colman started producing bulk drugs in the 1970s. By the late 1970s, 31 out of the 63 TNCs e.g., Abbott, Fulford, SKF, U. S. Vitamins, Roussel etc. were yet to produce bulk drugs. They relied on imported bulk drugs and those procured from domestic sources for their formulations. The companies which are engaged in bulk drug production also depend on these sources for a part of their requirement of bulk drugs for formulation purposes. For 35 TNCs, which accounted for 89 per cent of the total formulation sales of the TNCs in 1978,¹¹ we found that they used on an average Rs. 238.5 million worth of imported drugs and Rs. 339 million worth of bulk drugs manufactured by other firms in India during 1976/76-77 and 1977/77-78. These amounted to about 22.3 per cent and 31.8 per cent, respectively, of the total bulk drugs of Rs. 1067.3 million consumed by them. Their own production accounted for the remaining 45.9 per cent.¹²

After FERA

One of the objectives behind the enactment of FERA in 1973 was the regulation of foreign capital in India.¹³ Before FERA, only a small part of the foreign corporate sector, viz. the branches of companies incorporated abroad, were statutorily recognised under the Companies Act, 1956 (Section 591). Neither the Companies Act, nor the Industries (Development

and Regulation) Act, 1951 or the Monopolies and Restrictive Trade Practices Act, 1969 made a distinction between companies incorporated in India but controlled by foreigners and those controlled by Indians. Under Section 29 of FERA, all non-banking foreign branch companies and those incorporated in India with foreign equity of more than 40 per cent, require the permission of the Reserve Bank of India to (a) carry on, (b) establish, (c) purchase shares of, and (d) acquire wholly or partly any undertaking engaged in activities whether of trading, commercial or industrial nature.¹⁴ The Guidelines announced for administering Section 29 laid down that foreign branch companies would have to register themselves in India with foreign equity not exceeding 40 per cent and companies incorporated in India with more than 40 per cent of foreign equity would have to reduce it to 40 per cent or less. This is applicable to all companies, whether engaged in industrial, trading or other activities, with the exception of foreign airlines and shipping, which would be treated on a reciprocity basis. Under certain conditions, exemptions were granted. Industrial companies, for instance, were allowed to hold foreign equity upto 74 per cent, if they were engaged in :

- (a) the core sector, i.e. the production of items specified in Appendix 1 of the Industrial Licensing Policy of February, 1973. These are items classified under 19 product groups, including drugs;
- (b) manufacturing activities which need "sophisticated technology", and
- (c) predominantly export-oriented industries, etc.¹⁵

The effect of FERA basically appears to have been to make a distinction between firms with foreign equity of more than 40 per cent and those with foreign equity at 40 per cent or below, and to restrict the growth of the former to specific areas. This amounts to discrimination against a segment of the TNCs, viz., those with foreign equity exceeding 40 per cent, in contrast to the policy of non-discrimination followed particularly in the 1950s and the 1960s. the Industrial Policy of 1977 stated that :

"after the process of dilution under this Act (FERA) has been completed, companies with direct non-resident investment not exceeding 40 per cent will be treated on par with Indian companies, except in cases specifically notified, and their future expansion will be guided by the same principles as those applicable in Indian companies."¹⁶

The TNCs with foreign equity above 40 per cent were free to reduce foreign equity to 40 per cent or below by public issue of shares to Indians without surrendering their control, and thus claim equal treatment with the indigenous sector, comprising of the firms solely controlled by Indians. The public issue of shares by the TNCs, which are oversubscribed several times, ensures wide dispersal of shares so that the new shares-holders are

not in a position to pose a threat to the control exercised already by the TNC in a Company. We have discussed elsewhere¹⁷ how these companies in the process of dilution of foreign equity are obtaining additional funds and also additional licences from the government for expansion. We have also tried to show that areas specified for companies not diluting foreign equity to 40 per cent or below are such that their growth is unlikely to be adversely affected.

Regarding drug firms, additional guidelines were announced by the government in the New Drug Policy, 1978 (NDP) for implementing the provisions of FERA. The entire product group of 'drugs and pharmaceuticals' is included under Appendix I of the Industrial Licensing Policy, 1973. Hence, all the drug TNCs were eligible to have foreign equity exceeding 40 per cent. But, meanwhile, the government had appointed the Hathi Committee, which submitted its report in April, 1975. The Hathi Committee recommended that :

"having regard to the present stage of development of the drug industry, for the purpose of FERA Guidelines, this industry should not be eligible for the preferential treatment given to items specified in Appendix I of the Industrial Licensing Policy of 1973. In view of the Committee, foreign undertakings operating in this country should be directed to bring down their equity to 40 per cent forthwith and further reduce it progressively to 26 per cent.¹⁸

The government in its NDP rejected the recommendation of the Hathi Committee and decided that only those TNCs which were engaged in manufacturing formulations alone or bulk drugs not involving "high technology" would have to reduce foreign equity to 40 per cent or below.¹⁹

The government also decided that licences to the FERA companies (those with foreign equity exceeding 40 per cent) would henceforth be restricted to high technology bulk drugs and related formulations provided (a) 50 per cent of the bulk drug production was supplied to non-associated formulators,²⁰ (b) the bulk drug was not reserved for the public sector or companies with foreign equity below 40 per cent,¹² and (c) the ratio of the value of bulk drugs consumed from own manufacture to the value of total formulation production, did not exceed 1 : 5.¹²² The government also declared that :

"In considering industrial licence applications, however, preference will be given to Indian companies (i.e. those with foreign equity 40 per cent or below) over MRTP units and foreign companies, (i.e. those with foreign equity more than 40 per cent) and in that order. Economy of scale, technology and pricing of products, however, would be the deciding factors" (the phrases within brackets ours).

Scope for Expansion of TNCs

Following the guidelines as discussed above, the government has permitted only 13 companies to have foreign equity above 40 per cent.²³ Thirty-five companies have already diluted their foreign equity to 40 per cent or below,²⁴ and hence as we have already mentioned, they would be treated at par with the indigenous sector, though they continue to be controlled by TNCs. The special provisions regarding industrial licences applicable to the FERA companies may not at all adversely affect their growth. They are eligible to expand the production of existing high technology drugs and also to take up the production of additional high technology drugs. In 1984-85, the country imported bulk intermediates and formulations worth about Rs. 198 crores.²⁵ Hence, there is enough scope for diversifying into new areas. Under the general policy of import substitution, the FERA companies can obtain licences for producing these drugs, if they decide to use high technology. Significantly enough, the definition of high technology is such that although the NDP aims at self reliance and growth of the Indian sector, the FERA companies can still obtain licences even in areas where indigenous technology is available. As proposed in the NDP, a committee was set up in 1978, consisting primarily of government officials, which formulated a set of 12 criteria²⁶ to identify high technology drugs. Applying these criteria, the committee came to the conclusion that 93 out of the 207 bulk drugs produced by the FERA companies involved high technology. If we go through the list of these drugs, we find that many of them e.g., Dapsone, Diazepam, Betamethasone etc.,²⁷ had been produced by the indigenous sector without any foreign technical collaboration. Whether a drug was being or could be produced by an indigenous firm was not at all considered by the committee. The government is actually yet to adopt a policy to ban the entry of FERA companies in areas where the indigenous sector is already engaged.

[Continued

Table 1

Year of establishment and commencement of formulation and bulk drug production by the TNCs in India circa 1978

Name of the Company ¹	Year of establishment in India	Year of commencement of production	
		Formulations ²	Bulk Drugs
1. Abbott Laboratories (India)	1946	1960	Not produced
2. Alkali & Chemical Corpn. of India	1938	1976-77	1965 ³
3. Anglo French Drug Co. (Eastern)	1923	Not before 1955 ⁴	Not produced
4. Bayer (India)	1958	1967	1968
5. Biological Evans	1953	Not before 1958 ⁵	1959
6. Boehringer Knoll	1959	Not before 1960 ⁴	1962-63
7. Boots Co. (India)	1929 (1944) ⁶	1949	1965
8. Burroughs Wellcome & Co. (India)	1912 (1948) ⁶	1950	1960
9. Carter Wallace	1968	Not before 1968	Not before 1968
10. Ciba Geigy of India	1928 (1947) ⁷	1947-51	1957
11. Cyanamid India	1947	1953	1961
12. E. Merck (India)	1967	Not before 1967	1973
13. Geoffrey Manners & Co.	1943	N.A.	Not before 1957 ⁴
14. German Remedies	1949	Early 1960s	1962
15. Glaxo Laboratories (India)	1924	1947	1956
16. Hoechst Pharmaceuticals	1956	1958	1959
17. Johnson & Johnson	1957	Not before 1957	Not before 1957

18. May & Baker	1928	1943	1948
19. Merck Sharp & Dohme of India	1958	1959	1959
20. Organon (India)	1967	1973	1970
20. Organon (India)	1967	1973	1970
21. Parke Davis (India)	1907 (1958) ⁶	1954	1961
22. Pfizer ⁸	1950	Around 1952	1956
23. Rallis India	1948	N.A.	During II World War ⁹ Early 1970s
24. Reckitt & Colman of India	1951	N.A.	Early 1970s
25. Richardson Hindusthan	1951 (1964) ⁶	1966	1967
26. Roche Products	1958	1961	1962
27. Roussel Pharmaceuticals (India)	1956	Not before 1956	Not produced
28. Sandoz (India)	1947	After 1958 ¹⁰	1959
29. Searle India	1967	1970	1969
30. Smith Kline & French (India)	1950	1963	Not produced
31. Uni-Sankyo	1970	N.A.	1970
32. Wander	1962	N.A. ¹¹	1964
33. Warner Hindustan	1963	1967	¹²
34. Whiffen (India)	1954	Not produced	Not before 1960 ⁴
35. Wyeth Laboratories	1960	1963	1963

Sources : GOI, "Indian Drugs Statistics, 1976-77" (mimeographed, New Delhi, Ministry of Petroleum, Chemicals and Fertilizers, 1978), pp.11-60, 237-51.

DGTD, Development Council (Drugs & Pharmaceuticals, 1964-65), (Comp.), *Indian Pharmaceutical Industry*, (New Delhi, The Compiler, n.d.), pp. 52-135.

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Drugs & Pharmaceuticals : Industry Highlights, Vol 4, No.6, June, 1981, pp. 214, 219 (for the year in which the first licence was obtained by Geoffrey Manners and Whiffens).

Information obtained confidentially from reports submitted by selected companies to a department of the GOI.

- Notes : ¹ The list is not exhaustive; see the text for the nature of the sample.
- ² The year of commencement of formulations refers to own production, not production under loan licence.
- ³ The bulk drugs plant of Akali & Chemicals, which is primarily a chemical concern, was commissioned in 1977-78, but the production of a single item — Phenothiazine — was started in 1965 (see OPPI, *A Growth Plan for the Indian Pharmaceutical Industry*, (Bombay, The Author, 1976), p.27)
- ⁴ The year in which the first industrial license was obtained.
- ⁵ The year in which the factory was established
- ⁶ Refer respectively to the years of establishment of a branch and incorporation of a separate company in India.
- ⁷ Ciba (India), which had a pharmaceutical division was established in 1928 and Ciba Pharma (as the present company was then known) in 1947.
- ⁸ The row refers actually to Dumex since Pfizer started its operations in India by acquiring the former in 1958.
- ⁹ Refers to Teddington Chemical Factory; which was merged with Rallis in 1961-62 (see text).
- ¹⁰ The year in which the company took up the installation of a factory.
- ¹¹ Manufacturing under loan licence was started around 1964.
- ¹² A plant to manufacture basic Chemicals such as Gamma Picoline, Beta Picoline, etc. was started in 1969.

— Continued

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1. "Facts about delicensing of drugs", in *The Economic Times (ET)*, Calcutta, 30 August, 1985, pp. 4-5.
2. Actually in the early 1970s, even before the enactment of the FERA, the government showed signs of retreating from its policy of total non-discrimination between foreign and indigenous enterprises. See "New licensing policy", in *ET Bombay*, 19 February, 1970 and GOI, Ministry of Industry & Civil Supplies, *Guidelines for Industries, 1975-76*, (New Delhi, Indian Investment Centre, 1975, pp. 28-31.
3. For the names of all these 63 TNCs, see Sudip Chaudhuri, "Manufacturing Drugs without TNCs : Status of Indigenous Sector in India", in *Economic and Political Weekly*, Bombay (EPW), Annual Number, 1984, Table 1. For the details of the criteria used in each case, see, Sudip Chaudhuri, "Indigenous Firms in Relation to the Transnational Corporations in the Drug Industry in India" (Unpublished doctoral thesis, Jawaharlal Nehru University, New Delhi, 1984).
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5. Michael Kidron, *Foreign Investments in India* (London, Oxford University Press, 1965).
6. B. Shah, "Pharmaceutica! Industry in India", in DGTD, Development Council (Drugs & Pharmaceuticals, 1964-65) (Comp.), *Indian Pharmaceutical Industry*, p.6.
7. OPPI, *A Growth Plan for the Indian Pharmaceutical Industry* (Bombay, The Author, 1976), p.32.
8. *Report of the Industrial Licensing Policy Inquiry Committee* (New Delhi, GOI, Ministry of Industrial Development, Internal Trade and Company Affairs, 1967), Main Report, p. 124
9. Calculated from, Operations Research Group, "Retail Store Audit on Pharmaceutical Products" (Boroda, The Author, Annual), December, 1978.
10. Dumex stands for Danish United Medical Export — a combine of 6 Danish drug manufacturers.
11. Calculated from ORG, "Retail Store Audit".
12. Calculated from the replies of the companies to a questionnaire from the Ministry of Petroleum, Chemicals & Fertilizers, New Delhi, 1978.
13. Evidence of I.G. Patel (Secretary, Ministry of Finance, GOI), *Joint Committee on the foreign Exchange Regulation Bill, 1972 : Evidence* (New Delhi, Lok Sabha Secretariat, 1973) P. 128.
14. *Foreign Exchange Regulation Act, 1973* (New Delhi, GOI, Ministry of Law, Justice and Company Affairs, 1975), Section 29 (1), p. 18.
15. GOI, Ministry of Industry and Civil Supplies, *Guidelines for Industries, 1975-76*, pp. 152-56.
16. Text of Industrial Policy announced on 23 December, 1977 reproduced in GOI, Ministry of Industry, *Guidelines for Industries : Part I, Policy and Procedures* (New Delhi, Indian Investment Centre, 1979), Section II, p. 14.
17. Sudip Chaudhuri, "FERA : Appearance and Reality", in *EPW*, 21 April, 1979.

18. *Report of the Committee on Drugs and Pharmaceutical Industry* (New Delhi, GOI, Ministry of Petroleum & Chemicals, 1975), p. 98.
19. Text of NDP as reproduced in GOI, Ministry of Industry, *Guidelines for Industries: Part I, Policy and Procedures* (New Delhi, Indian Investment Centre, 1982), Section II, pp. 20 - 40.
20. The corresponding percentages fixed for the public sector, the MRTTP companies and the remaining companies are 40 per cent, 50 per cent and 30 per cent respectively.
21. Such lists were specified in the NDP.
22. The corresponding ratio fixed for the companies with foreign equity below 40 per cent is 1 : 10, provided imported bulk drugs do not constitute more than one third the value of total bulk drugs consumed for the purpose of formulating drugs.
23. These are : Bayer, Boots, Burroughs Wellcome, ciba Geigy, Gyanamid, Hoechst, Johnson and Johnson, Merck, Sharp & Dohme, Organon, Pfizer, Roche, Sandoz and Wyeth (see Answer of the government to Question No. 2633, Rajya Sabha, New Delhi, 21 December, 1981).
24. "Facts about Delicensing of Drugs", In *ET*, 30 August, 1985, p. 5.
25. Source : Ministry of Industry, New Delhi.
26. The "main" criteria formulated by the Committee are : (1) Isolation and extraction involving sophisticated processes such as counter current liquid extraction, repeated chromatography or narrow cut fractionation (2) Fermentation processes; use of enzymes for chemical transformation (3) Steps of operations involved in a chemical synthesis (4) Reaction temperature above 250°C or below (-) 30°C (5) Reaction pressures of 10 atmospheres and above (6) Use of potentially explosive material (7) High temperature vapour phase catalytic processes (8) Use of toxic materials (9) Purification and separation by different types of sophisticated technique (10) Careful on line process controls (11) Degree of Sophistication employed to ensure health safety and quality and (12) New Drugs discovered in India involving detailed pre-clinical laboratory and Clinical trials. (Answer of the government to question No. 1798, Rajya Sabha, New Delhi, 7 September, 1981 (mimeographed)).
27. For details, see, Chaudhuri, "Manufacturing Drugs".

Delicensing and Abundance of Essential Drugs A Myth

N. Mrinalini*

Essential drugs have always been in short supply. Technology cannot be cited as a constraint as most of them are produced in India and many of them are even produced in the Small Scale Sector.

Government announced the initial delicensing of 12 drugs in March 1986, which was followed by another 82 drugs in June. Hence, it amounts to 94 drugs. The list is given in Appendix 1.

The objective behind such a policy is stated to be : to increase the production and availability of essential drugs. In this paper an attempt has been made to see whether such an objective can be fulfilled, and also its possible ill effects have been highlighted.

For analysis, the delicensed drugs have been categorised into Category I, II and III drugs and also the sectoral reservation has been mentioned in Appendix 2. Category I, II and III are classified as 'life saving', 'essential' and 'non-essential' respectively. Mark ups allowed on these categories for purposes of pricing are 40%, 55% and 100% , respectively. It is found that out of the total delicensed drugs, 13 are from Category I, 10 from Category II, 52 from Category III, and two intermediates for the production of Chloroquin.

After the 1978 drug policy, sectoral reservations were introduced. Before this, all the drugs were open for all sectors, without the stringent price control introduced after the 1979 DPCO. This in no way gave a better position for the essential drugs production or availability. These drugs were imported in large quantities even then.

In Appendix 3, the total capacity registered/licensed along with their production is given. From the table one clearly observes that in the case of nearly 12 drugs of Category I and II, the capacity is not fully utilized, whereas in the case of Category III drugs like, Metronidazole, Sulphamethoxazole, Ethambutol, Salbutamol etc., the capacity is over-utilized. Delicensing the Category I and II drugs along with others in Category III, will in no way ensure the availability of these Category I and II drugs.

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There are also cases where the Small Scale Sector has made significant contribution. In the case of Chloramphenicol, DEC citrate, Phthalyl sulphathiazole, Piperazine, INH etc., drugs of Category I and II, their contribution has been almost equal to or more than the organised sectors. Even in the Category III drugs like Mebendazole, Sulphamethoxazole, Trimethoprim, Ampicillin etc., their contribution is significant. As far as the Small Scale Sector is concerned, the delicensing can only hamper their production. In most of the above mentioned drugs, there has been a drastic fall in imports. (Appendix 4).

If we look at the four vital therapeutic groups of drugs i.e., anti TB, antimalarial, antileprotic and antihelmintic drugs, except for Ethambutol, in the rest of the cases, capacity is very much under-utilized. (Appendix 5). Majority of these drugs fall under Category I and II. In the case of PAS, a vital anti TB drug and Piperazine, an antihelmintic drug, the production has fallen drastically. More production licences were already being sought for Rifampicin (an anti TB/leprotic drug). As this drug is also delicensed along with PAS, one can very well understand the impact of such a delicensing.

Conclusion

Hence, one can conclude that the delicensing policy in no way ensures the availability of essential bulk drugs but opens doors for more irrational drugs to get dumped into the market. By delicensing, the Companies tend to opt more for Category III drugs. The availability of essential drugs could have been ensured by retaining sectoral reservation and capacity regulation, by merely making it obligatory on the part of the Companies to produce them. But now, instead of such a compulsion, free hand is given to industries to go in for more irrational drugs. The concept of self-reliance and availability of essential drugs in abundance is again a thing to be pondered.

APPENDIX 1

List of Bulk Drugs Which Alongwith Their Formulations Have Been Delicensed

- | | |
|--------------------------------|---------------------------------|
| 1. Aspirin | 10. Calcium B. PAS |
| 2. Digoxin | 11. Chloramphenicol |
| 3. Hydrochlorothiazide | 12. Amodiaquine |
| 4. Isonicotinic Acid Hydrazide | 13. Chloroquine |
| 5. Thiacetazone | 14. Diethyl Carbamazine Citrate |
| 6. Tolbutamide | 15. Frusemide |
| 7. PAS Acid | 16. Glyceryl Trinitrate |
| 8. PAS Sodium | 17. Phthalyl Sulphathiazole |
| 9. Calcium PAS | 18. Prednisolone |

- | | |
|--------------------------------------|---|
| 19. Ether Anaesthetic | 51. Homatropine |
| 20. Halothane | 52. Chlorhexidine |
| 21. Thiopental | 53. Cetrimide |
| 22. Lidocaine | 54. Parachloro Metaxyleneol |
| 23. Procaine | 55. Promethazine |
| 23. Procaine | 56. Dexamethasone |
| 24. Nitrous Oxide | 57. Ethinyl Oestradiol |
| 25. Ibuprofen | 58. Norethisterone |
| 26. Chlorpheniramine | 59. Glybenclamide |
| 27. Epinephrine | 60. Chlorpropamide |
| 28. Mebendazole | 61. Neostigmine |
| 29. Bephenium Hydroxy Naphthoate | 62. Suxamethonium (Succinyl Choline Chloride) |
| 30. Metronidazole | 63. Ergometrine/Methyl Ergometrine |
| 31. Ampicillin | 64. Oxytocin |
| 32. Sulphamethoxazole | 65. Amitriptyline |
| 33. Trimethoprim | 66. Imipramine |
| 34. Erythromycin | 67. Trifluoperazine |
| 35. Ethambutol | 68. Aminophylline/Theophylline |
| 36. Pyrazinamide | 69. Salbutamol |
| 37. Griseofulvin | 70. Ephedrine |
| 38. Hydroxy Cobalamin/Cyanocobalamin | 71. Vitamin A |
| 39. Dextran | 72. Vitamin D |
| 40. Isosorbide Dinitrate | 73. Vitamin C |
| 41. Propranolol | 74. Pantothenates |
| 42. Verapamil | 75. Ferrous Salts |
| 43. Hydrallazine | 76. Chlorpromazines |
| 44. Methyl Dopa | 77. Hydroxy Theophylline |
| 45. Neomycin | 78. Doxycycline |
| 46. Bacitracin | 79. Diazepam |
| 47. Betamethasone | 80. Cephalixin |
| 48. Benzyl Benzoate | 81. Cephradine |
| 49. Sulphacetamide | 82. Cephaloridine |
| 50. Pilocarpine | |

List of Items Delicensed on March 16, 1985

1. Rifampicin
2. Dapsone
3. Clofazimine
4. Primaquin
5. EMME (Ethoxy Methylene Malonic Ester)
6. Novaldiamine
7. Insulin
8. Anti-Cancer Drugs
9. Vitamin B
10. Norgestral
11. Piperazine
12. New Bulk Drugs developed through indigenous research.

APPENDIX 2

	Category	Open For	Total
1. Aspirin	I	All	Total 13 Cat. I
2. Digoxin	I	All	10 Cat. II
3. Hydrochlorothiazide	I	All	52 Cat. III
4. INH	I	IS	2 Intermediates
5. Thiacetazone	I	IS	
6. Tolbutamide	I	All	
7. PAS Acid	I		
8. Calcium PAS	I		
9. PAS Sodium	I	IS	
10. Calcium B PAS	II		
11. Chloramphenicol	II	All	
12. Amodiaquin	II	All	
13. Chloroquin	II	All	
14. DEC Citrate	II	IS	
15. Frusemide	II	All	
16. Glyceril Tri-Nitratio	II		
17. Phthalyl Sulphathiazole	II	IS	
18. Prednisolone	II	All	
19. Ether	III		
20. Halothane	III		
21. Thiopental	III		
22. Lidocaine Xylocaine	III	IS	
23. Procaine	III	All	
24. Nitrous Oxide			
25. Ibuprofen	III	All	
26. Chlorpheniramine	III	All	
27. Epinephrine			
28. Mebendazole	III		
29. Bephenium Hydroxy Naphthoate	III	IS	
30. Metronidazole	III	IS	
31. Ampicillin	III	IS	
32. Sulphamethaxazole	III	All	
33. Trimethoprim	III	All	
34. Erythromycin	III	IS	
35. Ethambutol	III	All	
36. Pyrazinamide	III		
37. Griseofulvin	III	IS	
38. Hydroxy Cobalamin			
39. Dextran	III		
40. Isosorbide Dinitrate	III		
41. Propranolol	III		
42. Verapamil			
43. Hydrallazine			
44. Methyl Dopa	III		
45. Neomycin	III		

46. Bacitracin	III	
47. Betamethasone	III	
48. Benzyl Benzoate		
49. Sulphacetamide	III	
50. Pilocarpine	III	
51. Homatropine	III	
52. Chlorhexidine	III	
53. Cetrimide	III	
54. Parachloromethaxyleneol		
55. Promethazine	III	
56. Dexamethasone	III	
57. Ethiny Oestradiol	III	
58. Norethisterone	III	
59. Glybenclamide	III	IS
60. Chloropropamide	III	IS
61. Neostigmine		
62. Suxamethonium		
63. Ergometrine		
64. Oxytocin	III	
65. Amitriptyline		
66. Imipramine		
67. Trifluoperazine		
68. Theophylline/Amino	III	
69. Salbutamol	III	
70. Ephedrine	III	
71. Vitamin A	III	
72. Vitamin B	III	
73. Vitamin C	III	IS
74. Pantothenates	III	
75. Ferrous Salts	III	
76. Chlorpromazin		
77. Hydroxy Theophylline	III	
78. Doxycycline	III	IS
79. Diazepam		IS
80. Cephalexin	III	
81. Cephadrine		
82. Cephaloridine	III	
83. Rifampicin	III	
84. Dapsone	I	All
85. Clofazimine	III	All
86. Primaquin	I	
87. EMME		
88. Novaldiamin		
89. Insulin	I	
90. Anti Cancer	III	
91. Vitamin B-6	III	
92. Norgestrol	III	
93. Piperazine	II	IS

(IS = Indian Sector)

(All = Open for all)

Drug	Category	Open for	Total Capacity Regd./Licensed 30.6.85 (T)	1983-84	1984-85
Aspirin	I	All	1620	1,526	1,061
Digoxin	I	All	14.50 (kg)	12.49	17.13
Tolbutamide	I	All	95.93	24.06	28.75
Pas and Its Salts	I & II	IS	910.00	216.99	110.07
				53.29 (Org. Sec)	89.22 (Org. Sec)
Chloramphenicol	II	All	158.00	46.51 (SS)	70.63 (SS)
Amiodiaquin	II	All	96.00	23.41 (Org. Sec)	26.41 (Org. Sec)
Chloroquin	II	All	236.00	122.58 (Org. Sec)	147.39 (Org. Sec)
Dec Citrate	II	IS	26.00	29.13 (Org. Sec)	21.94 (Org. Sec)
				20.65 (SS)	19.01 (SS)
Frusemide	II	All	17.18	9.00 (Org. Sec)	6.73 (Org. Sec)
Phthalyl Sulphathiazole	II	IS	100	3.82 (Org. Sec)	9.94 (Org. Sec)
				12.67 (SS)	18.98 (SS)
Prednisolone	II	All	1,709 (kg)	1,846 (Monopoly)	1,682 (Monopoly)
Procaine	III	All	250	70.16	32.40
Ibuprofen	III	All	44.25	42.55	51.01
Chlorpheniramine	III	All	5.00	—	—
Mebendazole	III	All	17	7.15 (Org. Sec)	9.16 (Org. Sec)
				8.88 (SS)	11.32 (SS)
Metronidazole	III	IS	207	215.81	295.07
Ampicillin	III	IS	150	56.44 (Org. Sec)	104.69 (Org. Sec)
				67.20 (SS)	86.10 (SS)
Sulphamethoxazole	III	All	270.50	375.94	539.08 (Org. Sec)
				94.08 (SS)	99.76 (SS)
Trimethoprim	III	All	38.42	61.31 (Org. Sec)	46.53 (Org. Sec)
				37.97 (SS)	81.83 (SS)
Erythromycin	III	IS	88.00	31.51 (Org. Sec)	19.11 (Org. Sec)
				—	16.92 (SS)

Pyrazinamide	III	All		5.49 (Org. Sec)	2.62 (Org. Sec)
Ethambutol	III	All	99.00	3.86 (SS)	3.24 (SS)
				147.80 (Org. Sec)	205.50 (Org. Sec)
Propranolol	III	All	3.95	57.46 (SS)	63.75 (SS)
Methyl Dopa	III	All	34.00	4.57	5.37
Betamethasone	III	All	445 (Monopoly)	10.93	19.04
Sulphacetamide	III	IS	104	613.88	732.84
Dexamethasone	III	All	620 (Kg.)	39.71	47.46
Glybenclamide	III	IS	0.90	137.79	214.06
Chlorpropamide	III	IS	13.50	1.05	0.97
				19.69 (Org. Sec)	26.97 (Org. Sec)
Salbutamol	III	All	160 (Kg.)	33.83 (SS)	39.58 (SS)
				572 (Org. Sec)	512.00 (Org. Sec)
Ephedrine	III	All	32.65	75 (SS)	90 (SS)
Vita	III	All	119 MMU	2.17	6.19
Vitd	III	All	1,000 Kg.	61.24	60.58
Vite	III	IS	910.5	267.09	236.20
Doxycycline	III	IS	7.56	843.27	716.23
Diazepam	I	IS	4.38	1.66	4.32
Dapsone	I	All	43.00	3.43	5.73
Clofazimine	I	All	7.00	29.27	7.25
Insulin	I	All	2,780 MU	0.94	1.47
Piperazine	II	IS	115.00	2394	2541
				4.86 (Org. Sec)	5.20 (Org. Sec)
INH	I	IS	205	48.59 (SS)	23.58 (SS)
				105.72	127.70 (Org. Sec)
Thiacetazone	I	IS	12	46.79 (SS)	64.86 (SS)
				12.40 (Org. Sec)	20.39 (Org. Sec)
				25.45 (SS)	26.80 (SS)

Source: 1. Ministry of Chemicals and Fertilizers.

2. IDMA Annual No.

IS = Indian Sector.

All = Open To All

SS = Small Scale

Import Value (Rs. in lakhs) c.i.f.

	1980-81	1981-82	1982-83
Ethambutol	92.50	131.79	71.08
Doxycycline	77.14	110.00	24.16
Chloroquin	161.26	411.56	523.27
Chloramphenicol	215.48	41.21	Nil
Clofazimine	8.35	12.21	Nil
Aspirin	27.48	13.54	15.71
Ampicillin	519.10	210.82	137.13
Betamethasone	38.79	74.09	68.20
Chlorpropamide	Nil	Nil	Nil
Amodiaquin	Nil	Nil	Nil
Dexamethasone	91.37	98.24	114.93
Diazepam	Nil	Nil	Nil
Dapsone	4.96	34.21	73.90
DEC Citrate	Nil	Nil	Nil
Ephedrine	39.50	47.00	114.79
Griesofulvin	3.35	126.52	122.03
Glybenclamide	0.17	Nil	0.20
Ibuprofen	19.59	52.38	86.26
INH	3.07	Nil	Nil
Insulin	Nil	Nil	Nil
Mebendazole	NA	11.08	6.23
Metronidazole	4.03	4.19	3.85
Methyl Dopa	103.29	95.18	55.49
Piperazine	4.65	2.65	21.97
Prednisolone	66.11	61.35	187.60
Pyrazinamide	70.32	113.45	124.75
Sulphamethoxazole	277.98	2.02	3.96
Trimethoprim	56.90	1.90	1.07

Source : 1. IDMA Annual Number
2. Ministry of Chemicals and Fertilizers.

Drugs	Capacity as on 1. 4. 83	Production		Capacity as on 30. 6. 85	Production	
		1980-81	1981-82		1983-84	1984-85
INH	472.56	129.20	110.40	205.00	105.72	127.70
Thiacetazone	152.60	8.44	13.98	12.00	12.40	20.39
PAS	790.00	281.11	154.78	910.00	216.00	119.99
Ethambutol	203.	24.87	66.92	99 (219)	147.80	205.50
Dapsone	63	21.05	25.61	43	29.27	7.25
Clofazimine	2	0.20	0.44	7	0.94	1.47
Amodiaquin	76	23.15	26.02	76	23.41	26.41
Chloroquin	176	34.62	58.96	136	122.58	147.39
DEC Citrate	52	18.99	18.43	26	29.13	21.94
Mebendazole	33	1.39	2.70	17	7.15	9.16
Piperazine	165	25.18	7.70	115	4.86	20

Pharmaceutical Nationalism And A People Oriented Drug Policy

V. R. Krishna Iyer*

I. The Battle for Pharmaceutical Swaraj

The right to health for all mankind by the turn of the century was the universal resolve at the Alma Ata Convention. What a boon to the Third World if the versatile marvels of modern medicine can be harnessed to shoot down human diseases with pharmaceutical missiles and enrich the right to life with the joy of good health! This freedom from disease has an egalitarian import in that for everyone, young or old, rich or poor, living in rural or urban conditions or in countries backward or advanced, this guarantee can be actualised in fact, not only asserted as goal. This happy reality is the material foundation of human longevity without which all developmental promises prove tantalising illusions.

Swaraj is everyone's birth right. And a people ailing and wailing through life, whole families and localities stricken with nutritional privation, entire communities victimised by disease and suffering, with penury and illiteracy keeping medicines and hospitals and curative processes beyond their active ken and reach and hope, see no meaning in *Swaraj* if the blessings of Freedom do not include the access to medical facilities and nutritional supplies as components of the right to life. The militant message to the managers of Power is clear. This Project *Arogya Swaraj* in Third World conditions has meaning and relevance only if it will benefit the weakest, the lowliest, the most marginalised, in short, the Fourth World of havenots within the hapless Third World. Do remember we have many millions of them in our midst. With all our boasts of medical conquests and hopes of therapeutic advances, we are a sick society *so long as* the last and the least of our babies and mothers, brothers and sisters, aged and invalid, are afflicted with avoidable or curable disease and disablement. In this battle for universal health we must never forget the great heritage of medical pluralism India has handed down over the ages. To bastardize this proud, precious and proven indigenous health culture, and to lust for the West as the best, is a morbid moral-mental colonialism. Likewise, to despise

pharmaceuticals manufactured in India as genetically degenerate and to venerate imports from the white West as a superior race of medicines is therapeutic opium, a sort of drug apartheid in reverse propagated by the cure-all multinationals among the doped classes of our country whom the simian masses imitate. Deliverance from disease as a national policy must be honed on the whetstone of Indian availability of therapy to the needy, however small he be. Such a militant national movement is a constitutional fall-out from the right to life, freedom of movement, expression, profession and nutrition (see Parts III and IV). It is a component of that comprehensive social justice promised in the Preamble to the people of our Socialist Republic. If the nation is to redeem the tryst, several integral imperatives must figure in our plan of Health for All by 2000. The strategies of patriotic therapeutics embracing the millions must —

- (a) *prevent* disease and *promote* health;
- (b) activate, modernise, synthesise in eclectic spirit and inject with scientific research all the systems like ayurveda, siddha, unani, homeopathy and the wonders of yoga and above all, make the medical discoveries of Western, Soviet and Chinese systems available to Indians;
- (c) Indianise and democratise the manufacture and distribution of pharmaceuticals to match the socio-economic conditions of India. *The masses matter.*
- (d) enliven our medical practitioners' and specialists' sensitive commitment to the people in the field of malady-free health;
- (e) broaden and brighten our pharmaceutical manufacturing potential both in the public and the private sectors so as to strengthen our iatrical self-reliance;
- (f) build up an extensive infra-structure for distribution and delivery of drugs and medicines at moderate prices to everyone, everywhere in the country;
- (g) undertake research and development oriented on the curative urgencies of our masses and geared to the goal of the good health of our people tragically subject to endemic and epidemic afflictions.

Our social engineering of national pharmaceutical justice *for all* must be sensitive and comprehensive, alive to the plural disabilities of the many-dimensional have-nots, numerically enormous but marginalised. However, it is heartening to notice that among the important objectives of the re-structured 20-point programme, 'health for all' has been significantly spelt out. Briefly, it states the goal but how do we get there? What are the logistic implications and production processes? Do we possess the national infrastructure for manufacture and distribution and delivery of drugs and recipes. Policies and perspectives raise problems, beyond lovely verbalism, if implementation, on the basis of democratic self-reliance and socialist

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sincerity, is the desideratum. Health for all and freedom from disease for every Indian human, as a therapeutic desideratum means that handicaps, economic, social, geographic, cultural, gender-based or age-related and other, shall be overcome, in reaching medical facilities and iatrical literacy to the humblest, the disabled and the voiceless citizens. This is the actualisation of the democracy of disease-free right to life. Not vegetable existence but unimpaired unfoldment of personality. Instantly, a few issues of living relevance arise, ideological, constitutional, infra-structural and so on, so that the egalitarian battle for pharmaceutical justice may be fought and won.

II. Constitutional Foundation for Pharmaceutical Policy

The democracy of medical remedies and the equal opportunity for health for all citizens, are imperatives implicit in our Constitution. The Preamble plus Arts. 14 and 21 mandate this equal right to healthy life, reinforced by the directive principles laid down in Arts. 39(e) and (f) as well as Art 47. The State's duty to ensure the health of the people, with a democratic concern for the poor and a socialistic assurance of medicinal facilities for those who need, is thus 'fundamental in the governance of the country and the State shall apply these principles in making laws.'

Bedrocked on the basic right to pharmaceutical justice for every Indian, as an incident of social justice, the implications have to be worked out and woven into a legislative garment, taking meaningful cognisance of economic and cultural realities and enforcement processes. The focus is on the common man, mobilisation of the people is the catalyst, the people factor is a dynamic consumer movement, and the keynote is medical relief within the reach of the indigent Indian in large numbers, illiterate, exploited and hoping against hope that the right to life, sustained by medical recipes, will be a pragmatic reality, not a paper promise.

The implications include a radical change in the national pharmaceutical policy from dangerous drift and soft disposition towards M.N.Cs to the dynamic implementation of the theme of the W.H.O. "Healthy living: everyone a winner". India has over 700 million people. The National Sample Survey, 1975 states :—

"One Indian in every five is a severe destitute, one in every three is a destitute and nearly half of the population of the country is below poverty line. In rural India, nearly 200 million people would spend less than Re. 0.39 per day on basic necessities."

The human condition has not improved significantly since; and so this harsh demographic reality of populous poverty must be an input in the new dynamic Drug Policy. Secondly, the Drug & Pharmaceutical Industry

in India is dominated by the *organised sector*, 80% of the market being cornered by it, the small scale sector sharing but 20%. The private sector, which consists predominantly of multinationals and is solely profit-oriented, is the major factor in production. The weaker section of the people being unable to buy expensive drugs, the profit-rapacious manufacturers ignore the disease of the proletariat and concentrate on the ailments and susceptibilities of the propertariat. The rurals and the tribals are thus condemned to medicinal 'untouchability' and 'unapproachability'. Even otherwise, the boost of brand names through publicity and the medical profession's foreign make prescriptions create a craving to purchase *videshi* stuff whatever the price. Importing baloney blends, bastard brands and dubious formulations, without promoting transfer of technology rooted in pharmaceutical *swadeshi*, nor organising Research and Development tuned to the iatrical requirements within the country, buying up the Health bureaucracy through suspect strategies and softening up consumer and political resistance by claque and cute techniques, marking up prices breaking the backs of the ailing millions of indigents, using glittering packaging, investing in aggressive publicity drives and robbing the innocent, the agrestic and the terminally ill, the pharmaceutical tycoons, with *mareecha* methodology, have drugged the drug trade and, through sharp practices, held India's health policy to ransom.

III. Hathi Committee Report and After

Since Independence the 'therapeutic' industry of India has been continuously subjected to pharmaceutical imperialism and even now there is an indigenous medical fifth column supporting multinationals whose propaganda offensive and professional gimmicks subjugate the market; the poor, though priced out, buying desperately beyond their means and the rich buying expensively even from abroad. Essential and life-saving drugs were made scarce or jacked up in price, and dangerous or costly but useless drugs dumped on the unwary victims, while the same stuff was banned as deleterious or phoney abroad! Subversive chaos in the therapeutic cosmos is produced by the giants of the medicine manufacturing and marketing business. For TNCs, business is business and social health of Indians is irrelevance. Glamourizing shoddy products, seducing doctors and health executives, why, committing polished offences of picking ailing pockets to achieve profit-oriented targets is business principle. To hold a whole people's health, by unscrupulous stratagems, as hostage to corporate dividends is a negation of Free India's tryst with therapeutic salvation.

This poignant situation led to the Hathi Committee which made certain moderately radical recommendations for the attainment of pharmaceutical *swaraj* as the foundation for the universal health pledge implicit in our Republic's Preambular Resolve.

It is well known that the indigenous industry has capability, but the multinational sector with global power to promote its appetites and capitalise on human suffering, charges high prices, markets products tabooed elsewhere, produces complex formulations to the accompaniment of a barrage of publicity, acquires patents to prevent Indian medicine-making, risks the health of the people with iatrogenic drugs, inhibits Research and Development and growth of the Pharmaceutical Public Sector within the country and indulges in violations of drug morals and legal discipline and salutary prescriptions and proscriptions. The medical profession itself is doped and duped by pamphlets, presents, grants and allied allurements. The Hathi Committee recommended nationalisation of the MNCs operating in the country and demanded a positive policy to ban brand names and other devices so as to help the Indian sector attain self-reliance and indicated other guidelines for the development of the Drug Industry within the country, compelling the foreign undertakings to abide by more stringent regulations including reduction of foreign equity. The Committee recommended that the small scale sector should be forbidden area for foreign companies and that penal action should be taken against manufacturers of drugs without valid licences. A National Drug Authority was contemplated by the Committee.

The multinationals and Indian Pharmaceutical Quislings were able to rule the roost and scotch the Hathi Committee Report *both before and after March 1977* and today the unlimited profits and the high-tech blow-up of the multinationals continue. The National Drug Policy has never seriously come to grips with the organised power of the drug companies. They are a law unto themselves and the time has come for an immediate legislation of a comprehensive nature to make the indigenous pharmaceutical industry, particularly the Public Sector, an instrument of the National Health Policy with its democratic, socialist compulsions, flushing out hostile foreign firms and liberating medical nationalism from the dependencies syndrome.

Pharmaceutical titans play havoc

The pharmaceutical titans, even in the U.K. and U.S.A., play havoc, with human life. The Thalidomide cases in England prove the difficulty of enforcing product liability even when genetic horrors are perpetrated. The U.S. is the paradise of big pharmaceutical corporations which silence governmental watch-dog agencies by money power so that policing departments like F.D.A. neither bark nor bite. After citing cases of medicinal disasters caused by the corrupting power of the drug industry, Mintz and Cohen refer to the massive promotional campaigns in popularising dubious drugs (therapeutically irrational but exceedingly profitable):

"During the 1950s epidemics of serious and fatal staphylococcus infections were widespread. The most prominent cause was an exuberant over-prescribing of antimicrobial agents, the sulfonamides and the early penicillins, that allowed proliferation of strains of bacteria resistant to treatment. Although the epidemics subsided with development of a new class of penicillins, the semisynthetics, a threat of new proliferations of resistant strains became apparent in the late 1960s. Dr. Calvin M. Kunin, a specialist in the treatment of infectious diseases and chairman of a National Academy of Sciences-National Research Council review panel on fixed combinations of antibiotics, has warned of possible peril to "all society".

(America Inc pp. 24-25)

The Story of American Pharmaceutical Corporations and their stratagems is frightful indeed.

"The pharmaceutical industry was mainly responsible for creating the danger and, for fifteen years, perpetuating and expanding it. (To be sure, the Food and Drug Administration, which in 1970 finally secured a withdrawal of such irrational mixtures from the market, had disgraced itself by ever allowing the product to go on sale. This was an act so tainted that a federal grand jury undertook an investigation of the official involved. But the corrupting force was the industry; and the fount of the bitter-end resistance to withdrawal again was the industry).

One of the therapeutically irrational but lushly profitable mixtures combined, in fixed ratios two antibiotics, Penicillin and Streptomycin. The "widespread" and "indiscriminate" use of such products, which was a direct result of industry promotion, "almost led to disaster", Dr. Kunnin said. But not until June 1970, when further resistance would have been futile or counter-productive, was an administrative and court battle abandoned by Wyeth Laboratories."

(*Ibid* p. 25)

Massive promotional campaigns to purchase physicians to switch medicinal loyalties was tried even by reputed firms, like the Upjohn Company which introduced profitable harmful antibiotic mixtures.

"As if this was not enough, the Commissioner of the FDA testified that Panalba annually caused hundreds of thousands of needless injuries, a few of them lethal. Similarly the needless use of streptomycin, usually in combination with Penicillin or with a Sulfonamide, creates a needless risk of irreversible deafness in some patients, particularly children. In passing, it may be noted that this entire situation probably could not have developed had not the pharmaceutical industry been able to govern a significant element of the medical profession. Such control was achieved,

and is maintained, through devices that create dependency and stifle criticism, including gifts to medical schools and the placement of vast quantities of lucrative advertising in the *Journal of the American Medical Association* and other medical publications."

(*Ibid* p. 25-26)

Government succumbing to pressure of MNCs

Third World countries, conditioned into a pathology of credulity, are victimised by corporate power and the delinquencies of drug industries, coupled with successful hush money tactics. The right to life of the patient hangs on the police power of the State. But who will police the pharmaceutical police when drug companies are powerful.

The Hathi Committee Report has inspired Bangladesh to undertake radical changes in its Drug Policy, while in this country the Report has been virtually buried. All this adds upto a betrayal of the constitutional tryst with the health destiny of the Indian people. The urgent item on the agenda, therefore, is a comprehensive pharmaceutical code which will cover all aspects of health and medicine and embrace all systems of medicine including ayurveda, siddha, unani, homeopathy and allopathy.

It is Parkinson's Syndrome in drug policy that, under foreign pressure, Government is allergic to the Hathi Committee Report and dithers, delays, shies and even retreats allowing the hefty drug industrialists to hold to ransom the people's health. Pharmaceutical imperialism practised by covert and overt disinformation, trade terrorism and brain-washed professionalism is a menace to a patriotic drug policy.

The categorical imperatives of our Nationalist Drug Policy insist on busting the brand name baloney and the formulation monopoly held exploitatively by MNCs and extricating the people from the sky-high prices and the seductive dumping of non-essential drugs and medicines marketed through high-pressure propaganda by pharmaceutical empires. Nevertheless, it is a tragic betrayal of the people and a contradiction of the social justice content of the country's Drug Policy if the Doordarshan, a state-owned electronic media, surrenders to foreign-based pharmaceutical marketing mafia and surrenders T.V. "prime time" with the maximum gullible viewers across the nation to advertise with song and sex and superlatives dangerous or misleading drugs. This fatal failure to coordinate between the State's electronic media and the proclaimed theme of "Healthy Living : Everyone a Winner" is deplorable.

Hathi Committee recommendations

If the predations of the American Pharmaceutical Industry does overpower the Drug Controllerate, we may easily appreciate the vulnerability of the Indian consumer to Foreign Pharmaceuticals Incorporated

when it operates in our backward conditions. That is why the Hathi Committee — not a radical body but a moderate group with commitment to our national goals — recommended that foreign undertakings operating in India should be forced to bring down their equity to 40% with progressive reduction to 26%.

"The continued presence in this country of the highly profit-motivated multi-national sector can but promote only the business interests of this sector. Their presence in India, as a part of their global effort to capitalise on human suffering in an organised manner, must therefore cease as early as possible. We, therefore, strongly recommend that the multi-national units in the field of drugs and pharmaceuticals should be taken over by the Government. Such take-over will not create any dislocation in the production or distribution of drugs."

The proposal was that

"dilution of foreign equity should not take the form of dispersed holdings of the shares by large number of Indian nationals. It would be desirable for Government to purchase these shares either by public sector undertakings which are directly or indirectly connected with the manufacture of drugs/chemicals or by public financial institutions or by Government itself."

The establishment of a National Drug Authority referred to by the Hathi Committee has meanings only if it is entrusted with the responsibility of planning, procuring and producing drugs, supplying raw materials and co-ordinating the work of the various research and development institutions and agencies for distribution and delivery of essential drugs. Indeed, the Drug Authority must insist on the production of essential medicines (117) identified by the Committee. These essential drugs have to be up-dated since conditions have changed after the Hathi Committee Report :

"Although it would be desirable to regulate the import of raw materials for all formulations, a beginning should be made, whereby a central agency imports all bulk drugs and intermediaries needed for the 117 essential formulations identified by the Committee. This should be done by the National Drug Authority, who will also import raw materials and the ingredients required for these drugs and distribute them to the concerned manufacturers. The NDA will also stipulate the quantities of formulations that should be produced by the firms out of the basic drugs supplied to them and ensure that the manufacturers utilise them properly. The Committee also hopes that as the NDA expands, it would progressively improve and expand its activity in this direction."

"NDA would advise various manufacturers to regulate their production in accordance with the demand pattern and would also control the

distribution of the drugs, so produced, among formulators. To begin with, the bulk drugs indigenously produced and the chemicals required for the production of 117 items as identified by this Committee, should be pooled by the NDA and distributed to the manufacturers according to their requirements."

The conscience of the Report runs thus :

"(i) In appreciation of the fact that ill health has major socio-economic implications, the Committee feels that in a welfare state, availability of prophylactics and curatives should receive the highest priority on par with food and shelter. Production and distribution of drugs should, therefore, constitute an important social responsibility of the state.

The Committee is of the opinion that trade aspects of this vital industry should be divorced from the ordinarily accepted principles of trade for profit. Indeed, the Committee feels that trade aspects in this field should be limited only to the extent that the industry generates resources for its own growth and expansion through R & D where necessary to meet the increasing needs of the nation.

In order to achieve the above objectives, the Committee feels that leading role for production and distribution of drugs and pharmaceuticals should vest with the State. The Committee makes the following recommendations for providing to the public sector a leading role in the production and distribution of essential drugs and Pharmaceuticals."

(ii) "The Committee believes that health care has direct relationship with the socio-economic growth of the country and a welfare state should treat production, procurement and distribution of essential drugs, as a social responsibility just as important as ensuring supply of food and shelter.

With a view to tackling the problems of large scale production and distribution of drugs, the committee recommends the creation of a statutory body which may be called the National Drug Authority of India (N.D.A.)."

It may not be out of place to underscore a few more of the Committee's proposals.

"1 (a) Abolition of brand names in a phased manner, beginning with 13 single ingredient drugs identified by the committee.

(b) Production of all new single ingredient drugs to be under generic names;

(c) Non-proprietary names as recommended by W.H.O. from time to time should be adopted.

2. Rigid and uniform quality control of the drugs throughout the country should be ensured.

3. The drug control administration should immediately go into the various drug combinations and take prompt measures to eliminate irrational drug combinations.

4. In order to keep the medical profession well informed about new drugs and also to popularise the generic names, the Indian National Formulary must be revised and made up-to-date. Journals on the lines of the Prescribers Journals in U.K. and USA should be published under the control of an Editorial Board comprising leaders of the medical profession."

Drug Policy of 1978

The same deep concern is reflected in the Drug Policy of 1978 :

"The broad principles and objectives which Government have kept in view in formulating the new drugs policy are as follows :

- (i) To develop self-reliance in drug technology;
- (ii) To provide a leadership role to the public sector;
- (iii) To aim at quick self-sufficiency in the output of drugs with a view to reduce the quantum of imports;
- (iv) To foster and encourage the growth of the Indian sector;
- (v) To ensure that drugs are available in abundance to meet the health needs of our people;
- (vi) To make drugs available at reasonable prices;
- (vii) To keep a careful watch on the quality of production and prevent adulteration and malpractices;
- (viii) To offer special incentives to firms which are engaged in Research and Development; and
- (ix) To provide other parameters to control and rejuvenate this industry as a whole with particular reference to containing and channelizing the activity of foreign companies in accord with national objectives and priorities."

The thrust of the battle against MNCs which subvert our Public Sector pharmaceuticals and even the private manufacturing units is best expressed by the Union Minister Vasant Sathe while speaking to newsmen recently.

"The whole philosophy of capitalism is exploitation of man by man. Multinationals are just an extension of this philosophy."

Shri Sathe was more than right when he said :

"Our nation is committed to fight growth of capitalism, but somewhere along the line, this philosophy of Nehru got derailed. This is unfortunate."

The National Health Policy Statement, 1982 is people-oriented :

- (i) "India is committed to attaining the goal of 'Health for all by the year 2000 AD'

- (ii) The most urgent measures are required to be taken to ensure against the manufacture and sale of spurious and substandard drugs
- (iii) The available know-how requires to be adequately exploited to increase the production of essential and life-saving drugs and vaccines of proven quality to fully meet the national requirements, specially in regard to the national programmes to combat Malaria, T.B., Leprosy, Blindness, Diarrhoeal diseases etc. The production of the essential, life-saving drugs under their generic names and the adoption of economic packaging practices would considerably reduce the unit cost of medicines bringing them within the reach of the poorer sections of the society."

Apalling conditions of health

To understand the poignancy of the iatrical privations suffered by the weakest sector of Indians, namely the tribal belt, you will do well to read the recent report about leprosy stalking the Wynad tribal belt and families dying out without getting medical attention. A survey conducted by a team of Health Workers reveals that leprosy is endemic among the tribals in many areas of the Western Ghats. *Leprosy is curable and yet the tribals die of that dreaded disease.* Forty years of Independence! And yet curative medicines which can root out this disease have not travelled to the hills and these primitives, in conditions of acute poverty, constricted living space, close community living, rely on magical cures rather than modern medicine. The need for an effective delivery system, especially in the backward-most regions and populace cannot be overemphasised. Unfortunately, our National Drug Policy or rather Non-Policy caters more to the demands of the Pharmaceutical lobby with trans-national clout than to the health needs of the country's primitives and proletarians.

The national leadership will be guilty of criminality if it displays delinquent affection for the medicine manufacturing giants which have cunning ethics and circumventing tactics. Wrote A. N. Whitehead:

"Duty arises from our potential control over the course of events. Where attainable knowledge could have changed the issue, ignorance has the guilt of vice."

Please note that Corporations have no soul to be damned nor body to be burnt, with the result that the law limps or looks on with unconcern when lethal violations are committed.

Proliferation of dangerous drugs

In the suspect context of India becoming fatally hospitable to multi-nationals under the present regime, the people's consternation must be kindled by what the United Nations a few months back warned against :

"Pharmaceutical companies are manufacturing and marketing thousands of superfluous, ineffective or even dangerous drugs, according to a report released here yesterday at the 39th World Health Organisation congress.

More than 23,000 kinds of non-prescription medicines are on sale, though WHO has established a list of just 200 medicines that are essential to treatment of sicknesses worldwide, according to the report by an international consumers' cooperative, Health Action International.

Authors Andrew Chetley and David Gilbert, both Britons, accuse the pharmaceutical companies of wasteful policies that include misleading advertisements which can bring about unnecessary or even dangerous consumption of drugs.

For example, they say that 80 per cent of all diarrhoea medicines are useless in the treatment of acute diarrhoea, which claims the lives of some five million children yearly.

In addition, 65 per cent of all medicines against diarrhoea contains antibiotics, which are against WHO recommendations and have no effect on viral diarrhoea, the report said.

As much as 83 per cent of all 546 cold and cough medicines sold worldwide contain unnecessary additives. So do most of the 88 types of vitamin tablets and pain-killers.

Among the wide range of anti-inflammatory non-steroid medicines, 73 per cent are unsafe or have no therapeutic value. Further, they cost more than safer products, the report added.

Some dangerous drugs, such as for treatment of arthritis, are going on sale for five to 16 times the price of standard medicines, though the new brands are hardly more effective and the side-effects are as strong as the regular medicines, it said."

The Indian Sector of the Industry — I mean the Private Sector here — has, during the last one or two decades, demonstrated, under adverse competition and thug tactics of the foreign pharmaceutical mafia, its enormous potential for dynamic development and research reservoir. Our country passes through critical times, and dependence for essential and life-saving medicines on alien corporations is a grave national risk, especially when the foreign policy of certain Big Powers and their proxies tends to rubberise our sovereignty. National self-reliance in the iatrical sector and for manufacture of pharmaceuticals is a first charge. That is why the Hathi Committee, with sagacious statesmanship proposed a liberal policy of promoting Indian Companies to augment their production of bulk drugs and formulations :

"The Committee feels that in our anxiety to produce more drugs, we should not adopt a policy which places the Indian manufacturers at a

disadvantage. On the contrary, if the choice were between the foreign companies and the Indian companies, encouragement should be given to the Indian companies which are technically competent."

"The Committee suggests that the potentiality of foreign companies to exploit their names and smother the development of Indian sector of the industry should be blunted and a more purposeful and positive policy to help the Indian sector should be simultaneously implemented."

Do you know that foreign firms hardly produce drugs here, or part with their know-how, but acquire copyrights to forbid Indians to produce, and the MNCs import from outside?

No patriot in power can agree to make our pharmaceutical *swaraj* negotiable. It is heartening that our Prime Minister, whom I met but once for a brief while, showed deep concern over the pharmaceutical gangsterism of certain drug manufacturers and the need to control and discipline these profit-hungry 'privateers'. The new Drug Policy must, therefore, be more than national, it must be *nationalist*; it must be progressive and people-oriented, it must respond with profound concern to the problems of logistics, so that even the littlest Indian, in the neglected nook, is able to exercise his right to life through medical assistance. The question is whether we mean to implement the imperative of 'health for all' by 2000 A.D. The Director-General Dr. Halfdan Mahler said: "Health is the only race where everyone is a winner". *Provided* we have the political will and the practical skill.

IV. A National Health Code For Holistic Health Swaraj

No constitutional order can be sustained on mere executive orders or policy directive. You cannot punish without sanctions of law. You cannot license or cancel licence without the authority of law. You cannot search and seize, stop an industry or deny patents, regulate publicity or marketing methodology or otherwise police the drug business, compel Indianisation of technology and research, control invasion by foreign corporate power and so on, without statutory command. The rule of law is the rescue shelter of the victims of anti-social pharmaceuticals. The multi-dimensional nature of the law needed to meet the challenges of the Indian situation suggests two desiderata. For every legislation there has to be a legal theory. Thus, a pharmaceutical jurisprudence to secure therapeutic justice has to be evolved, bearing in mind constitutional fundamentals, socio-economic realities and the need for a Code of Health for all, particularly the lowliest, the lost and the last. The second imperative is a comprehensive code which deals with the drug industry in all its facets and dimensions,

Research and Development, self-reliance policy, criminalisation of violations, easy access to medicinal remedies, legal control of prices and distribution, regulation of publicity and advertisement, creation of pharmaceutical courts and locus standi for consumer organisations, prescription of penalties, nationalisation of drug industries, public sector monopoly for life-saving and essential drugs, reservation of certain areas of production to the small scale sector and so on. An administration with over-all authority to carry out the functions demanded by pharmaceutical justice, as outlined above, is also an important item on the legislative agenda. Basically, the call is to transform the Hathi Committee recommendations into foolproof legislation and incorporate all that is now available in the extant drug legislations, supplementing them by new provisions and instrumentalities, especially, involving the people through a vigilant consumer movement. A radical code for people's health is the desideratum, not governmental genuflexion before giant medicals from the West as now happens.

Nationalise MNCs

Among the programmes to be undertaken for ensuring pharmaceutical self-reliance is nationalisation of multi-nationals on a selective basis. A whole chapter dealing with nationalisation, informed by the philosophy of Indian pharmaceutical autonomy and social justice vis-a-vis health for all, will need to specify the principles guiding nationalisation, provisions for compensation and even transference of technology. Many other incidental matters, common in such cases, are all too familiar for the Indian Legislature. Nationalisation for the sake of nationalisation is a negative policy. But to safeguard self-reliance in the medicine manufacture field, and to inhibit invasion from abroad including product deception, and also to secure improved knowhow to match international standards, nationalisation serves a positive purpose. There are constitutional obligations when nationalisation is undertaken and even international norms which require compliance through statutory expression. The court is the watchdog where pharmaceutical violators manipulate the executive echelons or killers sell and the drug inspectorate slumber well.

Leading role for public sector

The public sector in the pharmaceutical field, as in other fields, must occupy the commanding heights of production and distribution. Where the physical and mental health of a whole people has to be preserved and promoted, where the battle against disease, nutritional deficiency and food fraud must be waged on a national scale and where the distributive network must possess a social responsibility and legal accountability, the public sector is an approved instrument, a national strategy to strangle

contra-national stratagems. It is not as if all the maladies of an industry are remedied by a takeover by the public sector, nor is inefficiency an inevitable attribute of public sector enterprises, as 'Coca Cola' politicians argue. The socialistic inspiration and the democratic commitment together with a higher national conscience in service can be generated in a public sector atmosphere more than in the profit-hungry private enterprise milieu. Law cannot provide the needed inspiration, but to run down the public sector is contrary to the spirit of the Republic. A creative patriotism and a functional conscientisation at the national level can be accomplished in the public sector, provided Art. 43 (A) of the Constitution making workers participants in policy formulation and management is made a statutory reality. Governmental-type bureaucracy benumbs the dynamics of public sector activity. Having regard to the high purpose of manufacture and marketing of drugs and medicines in the people's sector, cooperative or state-owned, new norms for the role of the workers may also have to be laid down. Even conditions of service must be formulated by joint discussion and decision and unionisation must, by statutory declaration, be not a monetarist grab but an advance towards fulfilment of targets in the truly socialist spirit. More autonomy with accountability, better selection of officer cadres, technical and administrative, based on social sensitivity and commitment to the people's sector, emphasis on merit as against political clout and covert nepotism, less bureaucratism and more involvement of workers through performance incentives and right to constructive criticism, fuller freedom of information for social action groups on the goings-on in the industry are the felt necessities of a healthy pharmaceutical system. We must transform public sector through dedicated cadres.

"The men who have reformed the universe have never accomplished it by changing officials but always by inspiring the people."

[Napoleon]

Strict marketing control

The *national sector*, even outside the public sector, requires statutory coverage. The Indian private sector and the FERA sector requires a new manufacturing-marketing discipline; and controls regarding packaging, quality and other commercial safety aspects, and appropriate declarations and guarantees to protect the consumer must possess statutory authority. Pharmaceutical frauds in myriad ways require to be countered by far more effective and expert methods than the dated Penal Code and the piecemeal Drugs and Cosmetics Act and a few other legislative fragments now do. A whole series of inspections, analyses, checks and tests of samples must be easily available if quality control is to be effective. An adequate infrastructure in this behalf is a matter of statutory provision, carefully

drawn up. Since corruption is terrible in the inspectorate and in the public analysts' offices, special penalties may have to be provided with people's organs being given access to the justice system.

An important component of the new Pharmaceutical Code is the formulation of policy and communication of information, taking note of the human handicaps, endemic disabilities, types of diseases, and other rural and tribal factors, which make exotic processes, including Research & Development of new drugs, inapplicable to Indian conditions. A surgical procedure in an advanced country may not work in Third World situations. Medicines administered according to sophisticated methods and preserved under conditions of western safety, may not work in the tribal areas and slum dwellings of India. Indeed, National Policy relating to the Drug Industry must be extremely sensitive to our oriental conditions, local variations and penurious situations, not to speak of the psychology of rural patients, and illiteracy and glamour for novelties. There are many other aspects of policy-making. But what is important to remember is that such decisions should not be left to the bureaucratic echelons, monopolists of medical expertise and ministerial bosses with little more than political equipment. Policy decisions and consequential pharmaceutical judgements must be preceded by national debates and dialogues involving scientists, experts, practical statesmen in the field and other leaders of public opinion including political parties. A regular Health Commission, continuously operating to form and change policies affecting medicine, health, food and nutrition and to monitor iatrical processes, obliged to function democratically and to consult concerned and informed elements in society may be a good idea — I mean an Advisory Body.

National Pharmaceutical Authority

Such an independent Commission of experts and leaders in public life is most desirable, because the influence on politicians and Sircar specialists of foreign pharmaceutical tycoons and big business houses in our own country may indulge in *suppressio veri* and *suggestio falsi*. Political clout makes the bureaucracy brittle and government then becomes a weak instrument against toxic pharmaceutical forces. Foods, for instance, are particularly susceptible to residual poisoning. Even otherwise, brand names which are automatically accepted in our country are found to be banned items in advanced countries. These unpalatable 'discoveries' can never reach the bureaucrat and the politician. Only scanning by informed and patriotic critics from among the public can unravel those covert adulterations, contaminations and poisonings as well as malpractices and manipulation by MNCs. Therefore, the Commission that I contemplate must have statutory powers and autonomy and must not include representatives of big business, Indian or foreign, lest the purpose fail. Maybe, token presence, not more.

I contemplate a National Pharmaceutical Authority (NPA) for India with State Boards and District Bureaus under it. The Central Minister in charge of Health will be the ex-officio President and the Directors General of each system will be the Secretariat. This Authority must have a democratic composition with representatives of both Houses nominated by the Speaker and the Chairman. There must also be representation for scientists, technicians and researchers. Social Action Groups (SAG), public interest litigation (P.I.L.) lawyers, legislative draftsmen and the Attorney General's nominee are necessary, since Law is a component of the Authority's operations. Likewise, there must be proper representation for consumer organisations, anti-vivisection groups and pharmaceutical literacy organs. The small-scale manufacturers of drugs and the working class employed in the drug industry must also be represented. The Authority must be autonomous and statutory and must have wide powers of control, superintendence and direction over Pharmaceutical industries and marketing agencies as well as Laboratories which do experimentations in the name of drug development.

The Authority must have the power to formulate principles of pharmaceutical ethics for the medics and marketing officials, backed by punitive sanctions for violation. The Authority must have power also to lay down policies and directives regarding Research & Development within the parameters of the National Drug Policy laid down by Government. It must have a special wing to monitor production and allied processes as well as distribution and use in hospitals, so as to avoid medical injuries and to improve performance. It must also have power to make recommendations to the Central and State Governments.

The NPA will also have a special wing for stimulating and overseeing R & D with indigenous drugs and related to Indian diseases, using Indian talent. Likewise, a special wing to organise rational drug propaganda and pharmaceutical education campaigns and to promote healthy environment, should be included.

V. An Iatrical Tribunal

An important part of the Code will deal with civil and criminal liabilities, sensitively attentive to usual and potential malpractices in the field. The position of the court is important. It will be under the Chairmanship of a specially sensitized and equipped High Court Judge with a collegiate character. There will be one representative with social action flair from the medical profession out of a panel furnished by the Indian Medical Council, another from researchers in the medical field, a third representing the consumers, nominated by the President. There may be Benches in every State according to requirements and powers of a High court will be

enjoyed by these courts, more or less like the Administrative Tribunals recently constructed or the English Industrial Tribunals. Lesser tribunals, mobile courts and so on are also a necessity.

There will be special procedures, simple and suitable, to meet the needs of pharmaceutical prosecutions. There will be simple evidentiary rules which will speed up trials and judicial remedies and will adopt novel methods so that real relief can be given to victims. Even publicity regarding punishments and for warning the public against common pharmaceutical crimes must also be included. There must be a medical police force specially trained in this branch of knowledge. The court must have power to deal with cases against doctors also, when it is connected with pharmaceuticals. It is proposed that there should be a training institute for judges, investigators and other personnel dealing with pharmaceuticals under the Code.

Judicial injustice

The need for Iatrical Tribunals is best brought out by the injuriously naive performance of some of our High Court Judges. Surely, many Courts have with finer perceptions, promoted and protected the community against health hazards caused by dangerous pharmaceuticals and governmental inaction. But it is equally true that legalistic judges unaffected by social concern and falling into erudite errors, act under forensic pressure from eminent counsel and unwittingly jeopardise public interest with horrendous consequences. For instance, a multi-national, which had been selling a drug at Rs. 20,000 per kg and had been directed, after departmental enquiries, by the Central Government under the Drug Price Control Law to sell at a fair price of Rs. 1800 per kg, had obtained a judicial stay of that direction and continued to sell at Rs. 20,000 per kg for a few years. It is an unfortunate footnote to this abuse that the same Drug Manufacturer had been willing, in the course of negotiations with the Health Ministry, to come down to Rs. 2200 per kg but angered by the fixation of Rs. 1800, had gone to court, got a stay from a gullible bench and continued to sell at Rs. 20,000/-! Similarly, drugs which had been banned as serious risks to life were still sold by obtaining stay from Court. Other like tragic instances can be cited of judicial injustices but the fact remains that medical literacy and social sensitivity are not a necessary part of the mental chemistry of the Judges, however high they be. Legal punditry in judicial summitry is no guarantee of wisdom and expertise in fields foreign to traditional legal education.

Legal profession must keep pace

The Bench and the Bar need not misunderstand my remarks as reflection on their competence and conscientisation. In a book 'The slumbering

Sentinels' Prof. Weeramantry says :

"Science and technology have burgeoned in the post-war years into instruments of power, control and manipulation. But the legal means of controlling them have not kept pace. Out-moded and out-manoeuvred by the headlong progress of technology, the legal principles that should control it are unresponsive and irrelevant. Legal strictures and concepts and people who work the system are proving unequal to the task of protection, in the midst of a set of problems without precedent in the law. Assumptions long regarded as fundamental no longer hold true. Values once held unquestionable no longer command acceptance. Procedures once adequate no longer yield results. Lawyers are out of their depths, their concepts out of touch, their techniques ineffectual. Sociologists, philosophers, economists, environmentalists, ecologists and politicians have sensed some of the dangers and prepared for them. Lawyers have been slow to do so, hampered by outdated concepts and methods."

And as for learned insensitivity, listen to Lord Macmillan's words to English Lawyers :

"Gentlemen, I appeal to you for once. Lift your eyes from your table; look beyond the window of your chamber. You will see the common man staring at you. He raises a question mark. The question mark raised by the common man may be silent and invisible today, but it may be vociferous and visible tomorrow."

Therefore, a trained judicial collegium, exercising pharmaceutical jurisdiction and exposed to a new know-how, is a *sine qua non* of health justice. There is need for lawyers specialising in pharmaceutical justice. A whole world of knowledge unfolds itself through studies and research literature which must be creatively converted into law-in-action. Lawyers' libraries now are innocent of such books. Senior lawyers and robed judges are learned in their orbits but are not guilty of familiarity with the burgeoning jurisprudence dealing with medical delicts, although there are classic works if one is inclined. Mark Twain once wrote, what applies to the Bench-Bar doyens, that a classic is "something that everybody wants to have read and nobody wants to read".

VI. The Right to Know

There must be freedom of information for every citizen to demand all relevant facts from manufacturing and marketing agencies, from Government and public authorities and from Research Laboratories. Every

activist citizen or Social Action Group (SAG) may claim information except such as, in public interest, is invested with great confidentiality. Where the right to know is not complied with on demand, the special tribunal may be moved to issue its writ. The right to know is the foremost component of the right to justice. Social action units must be clothed with status entitling them to get all facts from every source necessary to defend public interest. Gathering health intelligence is basic to public interest litigation.

"And ye shall know the truth

And the truth shall make you free". *John VIII : 32*

The democratic processes of social defense become dysfunctional if secretive recesses are permissible in public offices or private enterprises which affect public health and the public is kept in the dark about facts. Just see the stakes involved in keeping people ignorant.

"The government monitors the quality of drugs in circulation. Yet, the Indian Medical Association conservatively estimates that more than 10 per cent of the drugs in the country are spurious. Worse, patients — even in government-run hospitals — are not safe from this menace. Earlier this year, 12 persons died in Bombay's Jamshetjee Jeejeebhoy Hospital when administered contaminated oral glycerol."

(Smita Gupta — Express Magazine, April 6, 1986)

James Madison needs repetition :

"A popular government, without popular information or the means of acquiring it, is but a prologue to a farce or a tragedy; or, perhaps both. Knowledge will forever govern ignorance; and a people who mean to be their own governors must arm themselves with the power which knowledge gives."

VII. A Statutory Consumer Movement

There must be a whole chapter, in the Code contemplate, dealing with pharmaceutical consumerism. This is a specialised branch in a critical sector with novel know-how and creative strategies. Consumer movements must be encouraged by the NPA (National Pharma Authority) and even subsidised by it. All literature, relevant for literacy campaigns among the masses, must be made available by the Health Ministry at the Central and State levels. Social action groups (SAGs), with special accent on the drug industry and uses of pharmaceuticals, must also be recognised statutorily. They must be empowered to bring civil and criminal action as public interest litigation against pharmaceutical delinquents. They must be given free legal aid at the expense of the State. The SAGs must be clothed with

the right to demand banning of drugs or their use in particular situations or to check black-marketing. The Code must clothe SAGs with the right to be heard before every authority concerned. Functionally, SAGs must be brave and angry and be above suspicion. Human Rights sans mobilisation of the people will remain paper promises.

Only a consumer movement with access to intelligence and drive to enlighten the masses can make the people's right to health viable. A few illustrations will illumine my point vis-a-vis TNC villains in medicine-making and treacherous marketing. I am grateful to Prof. P. S. Sanghal for the material contained in his informative and excellent work on "National and Multinational Companies : Some Legal Issues". He argues :

"Some time back, Mr. Anwar Fazal, President of the International Organisation of Consumers Unions (IOCU), received two reports — one from the USA and the other from Hong Kong."

"The report from Hong Kong gave the results of a test on household insecticides conducted by the Hong Kong Consumer Council : 5 brands of the 12 tested by them were found to contain poisons exceeding the limits laid down by the British Insecticides Safety Scheme."

These five brands contained dichlofos (DDVP). Some brands also contained additional toxic chemicals that were considered unsuitable for household use.

"Mr. Anwar Fazal checked the markets in Penang and discovered that the same brand was being sold in Malaysia, without any statement of its contents whatsoever."

"This brainwashing of consumers in the USA and this wanton violation against the consumers in Hong Kong and Malaysia, and probably elsewhere, had been perpetrated by the Mobil Corporation — one of the largest transnationals in the world."

"In August 1972, at the 7th IOCU Congress in Stockholm, IOCU called for the application of consumer protection laws "not only to the home market but also to exports and the activities of multinational companies."

The Chloramphenicol Case :

"As the first response to this call, IOCU member organisations co-operated in a case study covering 21 countries. It was probably the first international consumer survey of its kind. The study illustrated in detail how a transnational company can and does market a drug abroad without such warnings of its dangerous, and even fatal side-effects as are mandatory in the home country. The drug was Chloramphenicol, also known by the other brand name of Chloromycetin, and the company primarily involved was Parke Davis.

"The results were shocking : You could buy Chloramphenicol over the counter in many countries. Of the 55 brand packs that were examined from 21 countries, not one warned against all the conditions in which its use was contraindicated. Many failed to warn against serious and possibly fatal side effects. Most extra-ordinary of all : there were wide variations in the warning given with the same brand produced by the same company in different countries."

(Introduction — pages xviii, xix & xx)

The promotional malpractices of MNCs are scandalizing :

"The report was launched by IOCU in 1975 with press conference in Geneva. IOCU's member organisations, consumer organisations all over the world, helped to publicise the problem in their countries and to draw the attention of government authorities to these facts."

"An update was carried out in South East Asia early in 1980. In May 1980, IOCU organised a press conference in Geneva, to which the update showed that the basic situation had changed only marginally. Ciba-Geigy, the principal firm involved, was invited. The proceedings of this press conference are now available. IOCU is continuing this campaign and has developed an Action Register of Problem Drugs which will form the basis for a continuing campaign in the pharmaceutical area. IOCU is developing an International Hazardous Products Warning Network — a kind of 'Consumer Interpol' — to systematically collate and disseminate information on hazardous products."

Sweetened Condensed Milk

"In 1979, the IOCU regional Office conducted a survey on the promotion of sweetened condensed milk (SCM) in 8 Asian countries. It was found that SCM was widely promoted as a suitable infant food; and Friesland Holland (a multinational cooperative), the Australian Dairy Corporation (a multinational government corporation), Nestle and Carnation Company, USA, were directly or indirectly involved in its promotion."

"The survey found that all of these multinationals practised double-standards, promoting its use as infant food in one country and warning against such use in another."

(*Ibid.* pages xxiv, xxv)

The operations of transnational Corporations are predations of Third World nations and the worst aspects of this subversion of self-reliant development is in the pharmaceutical zone. Our policy makers must understand the implications of generous invitations to these giants who rarely produce drugs within our country and use unscrupulous methods

of importation, under-cutting and benumbing of native potential. This victimisation must compel the Central Government to plan its National Drug Policy with *Swadeshi accent* and shun accession to the Paris Convention which is an international trap laid with global glitter of technological advantages, but will prove to be a strangle-hold on Indian production and a flood-gate for multi-national dumping of drugs and formulations to suit their insatiable monetarist appetite.

VIII. An Iatrical Ombudsman

It is proposed that a collegiate medical ombudsman be constituted who will have power to investigate wherever violations, delays, black-markets, spuriousness and other grievances are reported. The Central ombudsman may have subordinate agencies in every State with similar powers. They will operate independently, but will attend the meetings of the NPA.

India is a soft state where the MNCs do their danse macabre, intoxicated with profits from the suffering and dying Indian buyer duly doped with dubious publicity abetted by Government's media for ad-revenue. They buy up men who matter, bribe with jobs for relatives and so on. Even the medics abet.

Consumer protection bodies should exclude business lobbyists. The recent National Drug Policy Panel is reportedly compassionate to Drug Giants for obvious reasons and allergic to consumer activists. Again, consumer organisations must be entitled to intervene in Court cases to place the public point of view and move the ombudsman. Judicial awareness may be roused by them and that is important. A Court in the U.S., for example, is more alert because of consumerism. "A woman who lost the sensibility of her lips due to a defective lipstick was awarded 3 million dollars as damages." In India, the judge would be angry that such a case was brought at all.

It is said that a Consumer Protection Bill is being brought. Will it be a paper tiger? A legislative eye-wash rich with loop-holes, lacunae and logomachie potential as lawyers' paradise? Mobilisation of the people is the only recourse to pressure Government.

IX. Ban the Quack but Assure Holistic Health

A whole chapter on quack medicine and magic drugs is also necessary. Likewise, the various systems, apart from allopathy, like ayurveda, siddha, unani, naturopathy, and homeopathy, must also come within the broad authority of the NPA. Thus a medical drug jurisprudence and specialised jurisdiction is the desideratum. A revolutionary new approach to Health Care is the urgent imperative :

"The World Health Organisation has estimated that 60 to 80 per cent of the people in the Third World have, for all practical purposes, no access to modern medical services. During the 1970s it dawned on a large number of developing countries that they would not be able to provide health care for the majority of their people until the end of the twenty-first century if they continued along the old lines. A revolution in health care was required."

"Its goal is what WHO's Director-General, Halfdan Mahler, has called 'Justice in health'. 'Health care has to be equitably spread'. Mahler wrote in 1978 : 'Planners should not be asking, "To how many people can we provide good health care?" but "Given these resources, how do we use them to provide health care to everyone?".' In the new approach the emphasis in health care has to be shifted from care to prevention, from provision at Western standards to the urban privileged to satisfaction of the basic health needs of the underprivileged. Or, again as Mahler put it in his address to the thirty-first World Health Assembly in 1978 : 'The just distribution of health resources is as important as their quantity and quality. To reach a more equitable distribution it is necessary to pay greater attention to those least served, the social periphery, the disease-ridden majority. Our guiding principle should be the greatest health benefit to the greatest number of people at the lowest cost.'"

(The Third World Tomorrow by Paul Harrison, pages 227-228)

Technology geared to our needs required

There is no doubt that the complicated technology of the West is not needed, and a simplified set of medicines with appropriate technology will be adequate. In this context, Paul Harrison's observations are relevant :

"The cost of many proprietary Western drugs makes them unsuitable for the task of providing remedies for the poor majority. Yet most Third World countries continue to import them in great variety and quantity so that they may often account for 40 per cent of the health budget. An increasing number of governments are now cutting back their purchases to a smaller number of drugs free from patent restrictions, rather than more expensive brand-named products. The World Health Organisation has produced a list of just 200 essential drugs — chosen for their cost-effectiveness and safety — which would cover the bulk of health requirements in tropical countries though naturally each government would adapt this list to local circumstances. The reduced list allows bulk purchasing to cut costs and also makes the task of monitoring drug performance easier."

"Mass participation was another major emphasis. It is based on Mao's principle of following the 'mass line', trusting the wisdom and energy of the people themselves, which can work, and in the Great Patriotic Health

Campaigns, which successfully wiped out flies, mosquitoes and rats. Schistosomiasis or bilharzia was once endemic in eleven of China's thirty-three provinces and plagued some 35 million victims each year. It is caused by a single-celled fluke which passes out in human urine or faeces and spends part of its life-cycle in a particular species of water snail living in the paddy fields, before boring its way back into humans again through the skin of the feet. The incidence of this disease has been cut by two-thirds by a gigantic mass effort. Students and health workers educated people about how the disease was passed on. Then the ponds and paddy fields where the water snail lived were drained and the banks plastered in mud to suffocate the snails. Finally, safe methods of excreta disposal were introduced so the parasites' eggs could not pass into water with human faeces, which is used extensively as fertilizer in China."

(*Ibid.* pages 229 & 231)

Finally, it must be remembered that the 'first requisite of a gentleman' is to be a perfect animal! Health is national wealth and our Republic's strength depends on freedom from illness and assurance of positive health for everyone.

X. Epilogue

All these scattered thoughts gain coherence only if, in the proposed code, there is a prominent part on Directive Principles of State Pharmaceutical Policy. What should it contain?

1. Health for all shall be the early goal the State shall pursue.
2. Towards this pragmatic aim the State shall enact laws and enforce administrative schemes geared to ensuring the reasonable availability of drugs and medicines regarded as essential and life saving throughout the Territory of India at the same price which, by subsidy or otherwise, shall be within the means of the weakest sector.
3. The State shall promote pharmaceutical self-reliance and formulate and enforce measures of policing and pre-empting foreign invasion and infiltration so that the Indian Drugs Industry may develop without glamourised technological-pharmacological colonialism. Indian drug enterprises shall be helped to evolve a *Swadeshi* culture and to produce modern life saving medicines at cheap prices. The public sector shall be promoted to occupy commanding heights in production and distribution, the foreign sector shall be kennelled and the overall Indian Sector enlarged in production and improved in excellence. The State shall have due regard to indigenous systems and, in a big way, enhance their therapeutic status and integration with international pharmacopias through research and development projects and national

laboratories. Ayurveda, home-grown over millenia, has unique contributions to heal the diseases of humanity.

4. The participation and protection of the people, including consumers and workers, shall be a governing guideline. For viable and meaningful involvement of social action groups in this Peoples' Programme, schemes of consumerism, public interest litigation, medical literacy campaigns and mass mobilisation for community health shall be forged, and village level to national level discussions stimulated with demonstrations and activation of voluntary agencies devoted to creation of public health and para-medical cadres and dissemination of medical knowledge in rural and tribal areas.
5. A comprehensive catch-all penal and procedural and remedial legal system shall be drafted. The villains are hiding, the victims voiceless and policing agencies dubious. Who will police the police? The People. So it is that a broader access to justice mechanisms for citizens and specialised non-official bodies must be provided by the processual jurisprudence to be innovated if *pharma mafia* are to be manacled and sentenced.
6. The processes of law must be astute enough to outwit industrial licensing abuses and anti-people aspects of patent rights giving the State power and duty to defend the life of the common man.
7. The citizen's Freedom of Information is fundamental to his Fundamental Rights; and so, the State shall build legal provisions for unlocking the secrecies of pharmaceuticals, as well as facts stored in every public administrative office, research centre and computer. In an open society, secrecy is ill-health.
8. The State shall promote informed popular discussions to interdict neo-colonial pharmaceutical strategies and encourage *Swadeshi-oriented* social medicine strategies. Feedback from medics and pharma representatives and popular scientific groups will benefit the State's policy-making echelons.
9. In defending people's health the State shall so modify the patent laws and industrial licensing conditions as to forbid cornering of intellectual property to the detriment of the health of the community.
10. The State shall reform medical education so that pride in *Swadeshi*, not the opium of *Videshi*, becomes the passion in acquiring knowledge, and native collaboration in the chemical warfare by mighty pharmaceuticals may cease.
11. The Paris Convention is a multi-national menace to Indian medical industry and so, never be seduced into accession.

The drug industry drugs the bureaucracy. The *pharma mafia* with bewildering brands and dubious formulations prey upon Third World credulity and disease, but their remedy only aggravates the malady. The

time for a patriotic struggle to guarantee mental, moral and physical health against diseases and exploiters of diseases has come. The rule of law must meet this massive challenge because Art. 41 obligates the State "to make effective provision for securing the right to public assistance in cases of old age, sickness and disablement."

An Alternative Drug Policy

**All-India Chemical and Pharmaceutical
Employees Federation**

STATEMENT

1. The level of health of the people is interrelated with the Socio-economic conditions and political structure of the country. The high level of morbidity and mortality rates in India have their roots in the socioeconomic conditions of the country. Poverty, unemployment, hunger, absence of shelter, clothing and pure drinking water; illiteracy, ignorance and superstitions are the main social and economic contributory factors for the prevailing health situations of the people of India.
2. Supply of drugs is an essential tool in the health care system. Yet the production and supply of drugs are not related with the actual drug-needs of the people. The trade and industrial development are the guiding principles in the production and supply of pharmaceuticals in the country. As a result, a paradoxical situation exists today. While there is a scarcity of essential drugs, non-essential drugs and nutritive supplements are produced beyond the licensed capacities.
3. Even after 39 years of independence, majority of our people are deprived of the benefits of the scientific innovations of modern medicine. While a large number of people suffer and die in absence of proper and adequate medicines, in pursuit of profit motive the scientific innovations have been cornered by a few monopolistic interests.
- 3.1 Vast sections of our masses do not possess the necessary means to buy essential drugs. Unless steps are taken to remedy the situations which includes increasing the Government's health budget and increasing the people's purchasing capacity, the development of the local drug industry can never take place on the correct lines. Increasing exports and balancing the foreign trade cannot be substitutes for a domestic drug market.
- 3.2 The domestic drug industry cannot grow unless it is allowed to operate without the monopolistic grip. A national drug industry can develop only if it is made completely free from the stranglehold of the multinationals.

- 4.1 39 years' experience have proved that multinationals in the drug industry neither helped in capital formation through investment nor in establishing an industrial base for drugs and pharmaceuticals in the country through supply of technology and by contributing in indigenous R & D efforts. They resorted to transfer pricing, repatriate huge amounts through royalties, technical know-how charges and for other industrial property rights. They hinder the growth of a national sector, suppress their initiatives and R & D efforts and dominate the formulation market through aggressive marketing techniques.
- 4.2 The multinationals in drug industry produce, promote and sell hazardous drugs in which they are backed by the governments of their respective countries through permission of export of hazardous substances which were not approved for use in their own countries.
5. The bureaucratic control, absence of proper direction, mismanagement, top level corruption and the Government's policies have not allowed the Public sector in the drug industry to grow to take a leading position in the production and supply of drugs and pharmaceuticals.
6. Absence of encouragement to the national private sector, consisting mostly of small and middle scale sector, and their protection from multinational and monopoly pressure did not help the national drug industry to grow in the right direction.
7. In spite of having scientific and technological capabilities, which if fully exploited can make the country completely self-reliant in respect of technology for the production of all essential drugs for the people, the country is heavily relying on the supply of technology through licensing agreements with the multinationals.
8. High prices of drugs make them beyond the reach of a majority of the people. Profiteering on drug have been a constant source of exploitation by the multinational and monopoly drug firms.
9. Middlemen in the production and distribution of drugs have led to an increase in prices of drugs and profitability of drug firms.
10. High taxation rate by way of excise duties is a contributory factor in increasing the prices of medicines.
11. Drug information is not scientific. It is biased and is mainly based on the propaganda of drug firms with distortion of scientific truth. Under these circumstances and with a view to alter the situation in favour of the people, we give this Alternative Drug Policy to the people of India to fulfil their aspiration for a scientific, rational and democratic drug policy.

BROAD OBJECTIVES OF THE DRUG POLICY

Following are the broad objectives and principles of the Drug Policy.

1. Drug delivery system shall be related to the Health Delivery system.

2. Production and supply of drugs shall be aimed at fulfilling the real health-needs of the people.
3. Selective production and supply of drug shall be rigidly monitored on the basis of criteria fixed for the purpose.
4. Research and development; production and supply of traditional medicines shall be carried out to complement the use of modern medicines.
5. Public Sector — Central and State — shall be given the leadership role for R & D, production and supply of drugs.
6. Only small and middle sectors shall be allowed and encouraged to complement the activities of public sector for production and supply of drugs.
7. All multinational drug firms, even with minority foreign equity participation, shall be nationalised.
8. Drug firms, in any sector, under the control of monopoly houses shall also be taken over.
9. Rigid quality control shall be ensured to produce drugs of highest standard of quality.
10. A centralised procurement agency for the supply of drugs shall be established.
11. Hospitals, dispensaries and primary health care units shall be the main agencies for the distribution of drugs.
12. Drug traders shall be encouraged to retail drugs at the micro-level.
13. Drugs shall be sold only in generic names. All brand names on drugs shall be abolished.
14. Patent rights on drugs shall be abolished.
15. Prices of drugs shall be kept at the lowest possible.
16. All taxes on drugs, including excise and custom duties, shall be removed.
17. Uniform prices of similar drugs shall be ensured throughout the country.
18. R & D efforts, inhouse as well as in research centres, shall be ensured.
19. Indigenous technology shall be developed and improved to make the country completely self-reliant for the production of drugs.
20. Procurement and supply of raw materials for production of drugs shall be ensured through a central procurement agency.
21. Efforts will be made to eliminate import of bulk drugs and drug intermediates for the purpose of drug formulations in the country.
22. Unbiased and scientific drug information shall be provided by an expert committee, appointed by the government, to the medical profession, hospitals, institutions and health workers.
23. Vigorous efforts shall be made for economic and social upliftment of the majority of the people to improve the level of their health.

ALTERNATIVE DRUG POLICY

I. To make Drug Delivery System as a part of Health Delivery

1. Village-level Health Workers (VLHW) shall be recruited one for every 50 house-holds. VLH Workers shall be properly trained for health education. The elitist approach of health education shall be discarded. Education for prevention, eradication and control of prevalent diseases like diarrhoea, anaemia, amoebic dysentery, malaria worm-infestation, filaria, tuberculosis, goitre, night-blindness, etc. shall be undertaken.
2. VLH Workers shall also be trained to educate in simple house-hold treatment of diseases like diarrhoea, amoebiasis, fever, worm-infestation, goitre, night blindness, etc. He can also be an important link for identification and treatment of tuberculosis, leprosy and filaria.
3. The VLH Worker can also be trained for identification and utilization of easily available house-hold remedies with recognised herbs and medicinal plants.
4. VLH Workers shall not substitute primary health care units and dispensaries and shall be integrated in the primary health care system.

II. To Ensure Drug Supply to fulfill Health Needs:

1. To ensure that drugs are produced and supplied to fulfil the health needs of the people and not for industrial and trade development, the administrative ministry for drugs and pharmaceuticals shall be under the Health Ministry.
2. All irrational and/or hazardous drugs in single ingredient forms or in combinations shall be identified by an expert committee and shall be weeded out completely and expeditiously. No new drug or combination of drugs shall be permitted to be produced unless approved by the committee of experts.
3. Attention shall be given for Production of preventive medicines, including vaccines, to meet the national programme of eradication and control of communicable diseases.
4. A National Graded List of Essential Drugs shall be prepared by the committee of experts on the basis of following criteria.
 - (i) Drugs required for the treatment of communicable diseases affecting large number of people.
 - (ii) Life-saving drugs.
 - (iii) Preventive medicines.
 - (iv) Essential supplementary drugs.

III. To Monitor Selective Production and Supply of Essential Drugs;

1. To ensure production and supply of essential drugs in sufficient quantity a central drug authority in the Department of pharmaceuticals under Health Ministry shall be established. All aspects of production

and supply of drugs shall be considered, planned, implemented and monitored by this Authority.

2. Where more than one therapeutically equivalent drugs are listed in the graded list of essential drugs, following criteria shall be considered for selecting the drug for production.
 - (i) Availability of indigenous technology.
 - (ii) Already established manufacturing facilities wherever available.
 - (iii) Availability of raw materials within the country for production from more basic stage.
 - (iv) Cost factors.
 - (v) Benefit/risk ratio.

All the above criteria shall be taken together, weighed and decisions shall be taken by the Central Drug Authority on the advice of experts.

IV. For Supply of Traditional Medicines

1. Traditional medicines shall form an important part in the Alternative Drug Policy.
2. Traditional medicines should include Ayurveda, Unani and Tribal medicines.
3. During the British regime, colonisation of the country reduced the position of Indian traditional medicines. Thousands of years of human experience in development and utilization of traditional medicines were replaced by the big business interests under British patronage under the cover of modern scientific medicines while the position of traditional medicines were relegated to the position of superstitions.
4. However, any mystic formulation of traditional medicines should also be discarded totally. Scientific encouragement and support are essential for these traditional medicines. This does not mean similar scientific measurement of modern medicines should be applied to traditional medicines also.
5. This also does not mean to pose traditional medicines against modern medicines. Scientific discoveries of modern medicines are a great boon to human society. But these scientific discoveries were misused and over-emphasised for business interests.
6. What is required is proper utilization of traditional and modern medicines, with both playing complementary roles.
7. Supply of traditional medicines in the form of modern medicines should be discouraged.
8. A central co-ordinating body, under the Health Ministry, should monitor the research on traditional medicines. State Health Ministries should form research and production centres in as dispersed areas as possible at the proximity of utilization areas.

V. Providing Leading Role to the Public Sector and Small Scale Sector

1. Public Sector shall take up the main responsibility of research and

process development for drugs and pharmaceuticals. It also shall undertake production of bulk drugs from basic stages as well as produce drug intermediates. It shall also undertake production of formulations.

2. Public Sector shall supply technology, expertise and technical advice to private middle and small scale sectors and shall supply drug intermediates and bulk drugs to them.
3. Public Sector shall help in development of ancillary industry, supply technical advice and expertise to them, procure their products for utilization in the production process.
4. Government shall ensure supply of raw materials at reasonable cost to small and middle scale sector. If necessary, this should be subsidised. The banks and financial institutions shall extend financial help repayable in easy instalments and minimum interests. Adequate preventive measures shall be taken against their misuse.
5. The small scale sector shall not be asked to face competition with public sector. However, there should be free competition among the middle and small scale sector companies.

VI. *Nationalisation of Multinational and Monopoly Drug Firms*

1. It shall be the priority task under this policy to Nationalise all multinational drug firms, including those who are having minority foreign equity participation.
2. Drug firms, in any sector, under the control of monopoly houses shall also be taken over by the Government.

VII. *Ensuring Quality Control*

1. The Public Sector shall have their own in house rigid quality control system.
2. Middle and small scale sector companies also shall have their elementary quality control system. In addition, the Government shall provide a mechanism for quality control for small and middle scale sector companies for which the entire cost shall be borne by the Government. It, however, will be the responsibility of each manufacturer to get approval for each batch of product before marketing, certifying their quality.

VIII. *Drug Distribution*

1. Government shall establish a centralised agency for procurement and supply of drugs as per requirements in the hospitals, dispensaries and primary health care units. Such an agency shall have its centres for distribution of drugs at the sub-divisional level. It shall have its procurement centres in every state capital.
2. The Central Agency for procurement and Supply of Drugs shall also supply drugs to drug traders for retailing purposes. It shall help the small scale sector in distribution of drugs as expeditiously as possible

through it and help in quick cash return.

3. Hospitals, Dispensaries and Primary Health care units shall be the source of drug supply to the people. First category of drugs in the Graded List of Essential Drugs should be supplied free or at subsidised rates.
4. Drug traders will be encouraged to supply drugs through retail shops who shall procure drugs from the Centralised Distributing Agency at the sub-divisional level. Drug Traders will also be encouraged to supply drugs at the micro-level.
5. Manufacturers, both in public and private sectors, shall distribute drugs through the Centralised Drug Procurement and Distribution Agency only.

IX. *To Supply Drugs in Generic Names*

1. Drugs shall be supplied in generic names only. Brand name of drugs shall be abolished.
2. Simple and short generic names of drugs, both for single ingredient drugs and combinations, shall be formulated by appropriate authorities.

X. *To Abolish Patents Rights on Drugs*

Patents Rights on drugs shall be completely abolished and the Indian Patents Act shall be accordingly amended.

XI. *Pricing Policy*

1. All taxes, including excise and customs duties on drugs, shall be abolished.
2. Cost study of each drug shall be made by the BICP in one small-scale sector unit and in public sector unit. Subsidy at any level should also be accounted for.
3. Central Procurement Agency shall procure medicines at a price, fixed by the Government, which shall ensure reasonable returns to the small scale sector and allow reinvestment in Public Sector.
4. The distribution cost incurred by the Central Procurement and Distribution Agency shall be computed and added in the prices of the medicines.
5. The difference of procurement price of a product in the two manufacturing groups shall be accounted and reinvested in public sector units for providing technical assistance, and other facilities to the small scale sector.
6. Reasonable margin shall be allowed to the drug retailers in fixing the prices of medicines.

XII. *Research and Development*

1. Inhouse development efforts in private sector shall be aimed at increasing production for investment and further increase of employment; reduction of cost through process development and improvement of quality.

2. R & D efforts in public sector shall be for technological development not only for public sector, but also to provide technological assistance to small scale sector; for inhouse process development and shall be aimed at manufacturing from more basic stage, wherever required.
3. Research Institutions of the Government should be mainly responsible for basic research on drugs which should be aimed at —
 - (i) Improvement on existing drugs.
 - (ii) Discovery of new drugs
 - (iii) Development of technology for complete self reliance.
 - (iv) Research and development of traditional medicines.
 - (v) Balancing the treatment between modern and traditional medicines.
 - (vi) For maximum utilization of herbs and house-hold remedies as well as modern medicines through Village Level Health Workers.
 - (vii) For prevention and eradication of the endemic, epidemic and prevalent diseases, a central Co-ordination among these institutions shall be maintained under the Health Ministry.

XIII. Supply of Raw Materials

1. Procurement and supply of raw materials in private sector shall be ensured through a central procurement agency.
2. Efforts shall be made to eliminate imports of drug intermediates where alternatives are available within the country.
3. Raw materials and drug intermediates shall be supplied to middle and small scale sector on easy terms and conditions.
4. Ancillary industry for public sector shall be developed for supply of raw materials as well as packaging and other materials, wherever possible.

XIV. Scientific Information

1. An Expert Committee, appointed by the Health Ministry, shall provide unbiased scientific information to the medical profession, hospitals, institutions and health workers in an appropriate manner.
2. For the implementation of this policy, association, involvement and participation of the democratic mass organisations of workers and other concerned personnel shall be obtained on a continuous basis.
3. Under this policy, association, involvement and participation of the State Governments, Municipal Corporations, Panchayats and other local self-governmental bodies shall be obtained on a continuous basis.
4. Under this policy, advice and assistance of United Nations Organisations may be obtained from time to time.
5. Vigorous efforts shall be made for economic and social upliftment of the majority of the people to improve their level of health.

The Drug Policy — A Part of The Economic Policy of The Government of India

P. K. Ganguly*

The drugs and pharmaceuticals industry in India is under the stranglehold of Multinationals. The Multinationals control about 78 per cent of the drug production in India even after 37 years of Independence, and 16 per cent of the production is in the hands of the Indian private sector. Only 6 per cent of the drugs are produced in the public sector. Research and Development (R & D) in the Drug Industry consists merely of preliminary screening of different microbial strains from the Indian soil for production of life-saving Antibiotics. They are then shipped to the parent Companies abroad, products and technologies developed and then sold back to India at exorbitant prices — 5 to 6 times higher than that in the European countries. The prices of drugs are rising four times as fast as the GNP in many Third World countries.

Although the two big public sector drug units, viz., Indian Drugs and Pharmaceuticals Ltd. (IDPL) and Hindustan Antibiotics Ltd. (HAL), were mostly dependent on imported technology and imported strains for their production of Antibiotics, we can very efficiently strengthen our own R & D in close liaison with the National laboratories and the universities, achieve self sufficiency and also drastically reduce the prices of drugs.

Development of Drug Industry

India was one of the pioneers in the quest for scientific knowledge and developed various indigenous medicines. Dr. P. C. Ray and S. S. Sokhey were pioneers in this field. They made efforts to develop serums, vaccines, Pencillin, Streptomycin, Anti-Leptotic Drugs, and above all, the Public Sector. But the policy of wooing the Multinationals by the Government of India nipped the developing indigenous medicines and the process of indigenisation in its bud, exposing the people to international capitalist racketeering in drugs and pharmaceuticals. The motive of production being only profit, the needs of the people, the pattern of diseases in India,

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the problem of banned drugs and Research and Development have gone into oblivion.

In a short span of 35 years the drug industry in India has recorded a phenomenal "growth", producing drugs worth Rs. 1200 crores as compared to Rs. 10 crores in 1947. This is what the Government boasts of. About 60,000 drug formulations are sold in India. But according to WHO, and also the Hathi Committee, 80 per cent of the drugs are non-essential. A number of drugs available in India are banned in the parent countries of the Multinationals as they have been found to produce dangerous toxic effects. Even though under pressure from the trade unions and other organisations, the Government has formally banned some of these drugs, yet they continue to be sold in the market. Obviously, the Government was unable to withdraw the drugs due to pressure from the Organisation of Pharmaceutical Producers in India (OPPI), an organisation of the Multinationals. Apart from dumping their banned drugs in India, these "renowned" Multinationals produce large quantities of substandard medicines.

Dependence on Multinationals

Pointing to these realities, the Hathi Committee in 1974, by a majority decision, noted that the activities of the Multinational drug firms in India were anti-national and had recommended for their nationalisation. The All India Chemical and Pharmaceutical Employees Federation (AICAPEF) and the Federation of Medical Representatives' Association of India (FMRAI) have been consistently demanding Nationalisation of Multinationals. The National Seminar on Drugs and Indian People held at New Delhi in 1981 raised the same demand. But the Government of India has been allowing further collaboration and import liberalisation to woo the Multinationals, causing great danger to the life and health of the Indian people.

The drug policy of the Government declares that the Multinationals engaged in the manufacture of formulations or bulk drugs involving "high technology", need not dilute their existing foreign equity. This leads to a dangerous postulation that India cannot be self-reliant technologically, and has to depend continuously on imported technology from the Multinationals. The result is that the Multinationals not only dictate their terms to the Government but also function as a State in themselves. The Government has no machinery to prevent the entry of spurious, banned and substandard imports into the market. It is worthwhile to quote Justice Subramanyam Potty and Justice Padipuram of Kerala High Court here: "Between the lives of the citizens of this country on the one hand, and the loss that may result to the manufacturers and sales, on the other, the Government has chosen to view the latter of more concern".

Dangerous Shift In Economic Policy

This is only a part of the story concerning the drugs and pharmaceutical industry. The Government of India is a party to the Alma Ata Declaration of 1978 which called for Health for All by 2000 AD. In this respect we have to look into the overall socio-economic condition of the country and the Economic Policy of the Government. The New Economic Policy of the Government as announced last year makes many dangerous postulations. There is a major shift in this policy which virtually calls for disbandment of the public sector. In the 1956 Industrial Policy Resolution the Government declared that the public sector will play a dominant role, with the private sector playing a subsidiary role.

But since the Union Budget last year, the Government has actually reversed this policy. Shri Rajiv Gandhi commented that the public sector has over-stepped itself and now the private sector should play its role. With this understanding he wants to accelerate the process of industrial development in India by taking it to the "21st century" through high technology imported from the Western countries. So National planning has been abandoned and the new policy postulates removal of controls, denigration of the public sector, freedom for the private sector and opening the Indian market to the Multinationals. This single-minded pursuit will bring economic disaster to the country and the workers and the people will be exposed to the full blast of exploitation by the Multinationals and Indian monopolies.

But this is not sufficient to describe the shape of things that is in the offing. The Multinationals do not remain content with capturing the economic market only. They conspire to bring down Governments and establish their economic and political domination over the country. It was with this aim that the Imperialist countries, the World Bank and the IMF had been pressurising the Government since long to change its Economic Policy, to which the Government has finally succumbed. The Industrial Policy Resolution of 1956 was formulated with a view to containing the thrust of the Imperialists, and their tentacles, the Multinationals. This was a necessity and the Trade Unions and the progressive forces in the country supported it. The public sector in a Third World country like India, following the capitalist path of development, does serve the interests of the indigenous Capitalists but it is an instrument of defending the country against Imperialist penetration.

In spite of a great deal of mismanagement, the public sector contributed to defending the independence of our economy. In a number of cases, including the pharmaceutical industry, it was directly helped by the Soviet Union and other Socialist countries. Now the shift in the economic policy portends a danger to the freedom and independence of India

because the denigration of the public sector is not merely meant to appease the Indian monopolists but also to invite the Multinationals to help India in technological advancement. This has been done despite the fact that Indian technology and scientists are of sufficiently high standards and can develop without the help of Multinationals. This policy will place public sector undertakings under the technological and managerial control of foreign companies.

Need to Fight The New Policies

As already stated the drugs and pharmaceutical industry is already under the stranglehold of the Multinationals. The New Economic policy will lead the industry into the marsh. In pursuance of the New Economic Policy the Government has already declared that the public sector will not be developed in the drugs and pharmaceuticals industry. The New Drug Policy which was expected to be announced by the end of 1984 has now been inordinately delayed. The reason is that the Government is trying to "settle" the fight between the Indian Monopolists and the Foreign Multinationals as to who should get the lion's share of loot from the industry. In the process, the public sector that holds the minimum share of the industry, i.e., a meagre 6 per cent is going to die.

Under the above circumstances we have to look into the problem with an overall perspective of the economic policy of the Government. Since this policy goes against the interests of the scientists, Indian technology the entire people, and the country itself, it is necessary that a broad-based front be prepared without further delay to fight this policy and demand its reversal.

Health Policy and Drugs

*Prof. Gauri Pada Datta **

Introduction

The Health Policy of any Country depends on the socio-economic and political situation prevalent in that Country. As drugs are an indispensable component of health care, the Drug Policy of a Country cannot but be subservient to the Health Policy.

Health and Disease

Health is defined as a condition of physical, mental and social well-being of the individual. On the other hand, disease means a morbid condition of the body or mind. This is related to :

- (a) Internal resistance of the individual.
- (b) Exposure of the individual to exogenous noxious stimuli.
- (c) Nature, number and frequency of exposure to the causative organisms of disease and their virulence.

The internal resistance depends basically on nutrition which is further dependant on the nature, quality and quantity of food taken. Genetic factors also exert influence on the internal resistance. This, again, is not free from the influence of socio-economic and geographical factors.

The onslaught of external noxious stimuli depends on the environment in which the individual lives i.e. the sum total of housing conditions, disposal of human and animal excreta, his own health culture and education and availability of potable water. Last but not the least is the factor of education which includes General Education and training of health personnel like doctors, nurses, paramedical staff etc.

Thus it is clear that the cause of disease is multi-factorial and not unifactorial. Social stratification and socio-economic relations within a society are largely responsible for determining the health of an individual as well as that of the whole community. In a class divided society, the basic

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pre-conditions of good health are denied to the weaker sections of the society. The training of health personnel is also so oriented that it is geared to serve the interests of the dominant sections of society.

Distorted Priorities

In a Capitalist Society, the ruling classes realise the need for reducing mortality and morbidity rates. But this realisation is borne not out of some altruistic motives, but flows from the need to keep the working people healthy to the extent that ongoing production is not jeopardised. The creation of a lopsided infra-structure for health care to cover the felt need of the people, without trying to provide the basic requisites for good health, follows from such an attitude.

Concentration on the Curative aspect of Health and the emphasis on discovering newer devices for diagnosis and treatment of diseases with maximum precision without making the existing devices accessible to all, are reflections of the same attitude. This is further reflected in the imbalance in budgetary allocations, the uneven distribution of health personnel and the neglect of Preventive and Promotive aspects of Health.

A similar attitude is reflected in the Drug Policy too. A market is sought to be created by the drug Companies, by indoctrinating the people in the use of more and more drugs and diagnostic procedures. On the other hand, the people are seldom warned about the effect of misuse of drugs and possible iatrogenic effects.

Hathi Committee Recommendations Ignored

The Hathi Committee, instituted by the Government of India to review the production and use of drugs in the Country, reported in 1975 that total amount of drugs we produce and import can only satisfy the needs of 20% of our population. The Committee pointed that Multinational Drug Companies were exploiting our people, without making them aware of the ill-effects of drug resistance and the dangers of iatrogenic diseases. In spite of these reports, the Government has not changed its Drug Policy.

In a country where about 70% of the people live in the vicinity of the poverty line, a majority of the people have little access to health care. Nor do they have the necessary means to buy drugs required by them. Thus, the profits of the drug companies is derived basically from the purchase of drugs by the upper and middle sections of the people and to some extent by the State and Central Government Purchases for Public Health care. The indigent section of our population is affected because they have little access to the existing infra-structure of health care and also due to the existing drug policy which makes even life-saving drugs unavailable to them. Further, they are indirectly affected by the drainage of the national

exchequer due to diversion of funds from priority areas. This takes place due to over production, by the drug companies, of inessential and useless drugs while essential drugs are always in short supply. This is the basis of huge profits amassed by multinational companies at the cost of the health and lives of our people.

Health Movement Must be Part of Democratic Movement

It is heartening to note that medical representatives and a section of scientific workers and doctors are today pointing out the dangers of the present Drug Policy pursued by the Government. A significant section of our people have today become vocal against the exploitation by Multinationals. However, we must realise that the technical personnel and intelligensia, cannot by themselves bring about a change in the existing socio-economic relations. They must understand the political motive behind the Health Policy and Drug Policy of our Country, and educate the people about this aspect. Thus the health movement must form a part of our democratic movement. It should be the duty of the progressive sections of the people to organise a health movement and co-ordinate this with the movement for socio-economic and political salvation of our people.

India's Health Policy and Drug Scenario

Atul Dutta*

Even 40 years after Independence India does not have a Health Policy which is geared to the needs of the Indian people. What is lacking is the political will necessary to formulate and implement a 'people-oriented' Health Policy. The importance that our Government attaches to Health is evident if one studies the following table showing the per cent share of the Health Budget in successive Five Year Plans.

Plan Period	Per cent share of Health Budget in total Plan outlay
2nd Five Year Plan	3.30%
3rd Five Year Plan	2.60%
4th Five Year Plan	2.10%
5th Five Year Plan	1.40%
6th Five Year Plan	1.00%

Further, it is a pity that though the Government is unable to provide public health facilities to the entire population, private spending on drugs is taxed to the extent of 60 per cent. A medicine worth Rupee 1/- attracts 60P worth of direct and indirect taxes by way of import duty on raw materials, Excise Duty, State and Central Sales Taxes, and Excise Duty on packing materials and further Excise Duty, Sales Tax and Octroi on finished products. In our opinion a tax on medicines is a tax on sickness. All taxes on medicines should be abolished, so that drug prices are brought down.

Present Position vis-a-vis Availability and Price of Drugs

(Details in Annexure)

- Essential drugs are in short supply
- The market is flooded with drugs of non-essential and doubtful nature
- More than 60,000 formulations are available in the market
- New products are continuously being introduced in the market without proper evaluation of their usefulness

- Multiplicity of drugs in the market due to the same drug being sold under several brand names
- Unnecessary and high cost packaging are allowed even on common drugs like antacid, thereby artificially inflating the prices of drugs
- Unnecessary over-head expenditures are included in drug prices.

Drug Scenario. To achieve the objectives of a truly National Drug Policy and to provide guidelines for the formulation of an action programme, the following might be suggested for immediate action

1. A comprehensive list of the prevailing diseases should be made.
2. Elimination of all unnecessary, useless drugs, drugs of doubtful efficacy and harmful ones from the market.
3. Registration of essential drugs considered adequate for most therapeutic purposes as per suggestion of WHO. "150" drugs can suffice the basic need of our country.
4. There can be a supplementary list of drugs needed for Health Care by specialists.
5. A safety certificate is to be issued for individual products periodically on the basis of usefulness, essentiality and cost-effectiveness, and relevance to Health needs of the Country.
6. The selected essential drugs shall be given preferential treatment in terms of licensing, import duties, and often financial benefits.
7. A National Formulary to be prepared and published periodically which will include all the formulations allowed for manufacture, import or sale in the country.
8. Products such as, vitamins, mixtures, combinations drugs, combinations of antibiotics with other drugs, gripe water, cough mixtures, tonics, balms, digestive enzymes and other similar useless and/or non-essential products to be identified: Their production, licensing, registration should be carefully regulated.
9. The Drugs Act should be revised to suit the present need as visualised in the above recommendations. It should include :
 - (d) A system of registration of all medical products including Ayurvedic, Unani and Homeopathic medicines.
 - (b) Enforcement of standard manufacturing practices.
 - (c) Punishment by Summary Trial for offences.
 - (d) Drugs prepared for marketing should be processed through Drug Control Laboratories under Drugs Control Department.
10. To control prices of essential drugs, a reasonable basis of costing to be worked out and reasonable profitability to be taken into consideration. Costing should not include undue overhead expenditures, royalties and expenses in the name of technical bioavaila-

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bility. Only actual cost of packing materials should be taken into account.

11. A drug monitoring system should be set up to monitor availability of essential drugs and information on the same. Such information should be communicated directly to the Registered Medical Practitioners. The present form of detailing through medical representatives should be stopped.
12. Use of Brand Names should be completely stopped once and for all.
13. Nationalisation of all multinational corporations and monopoly houses.
14. The Drugs Advisory and Technical Advisory Committees at present are not fully represented by all the sections of the profession. For effective policies and programmes these bodies must provide representations to the bodies like Chemists & Druggists, Medical Representatives, Consumers forum etc., besides academicians, doctors, industrialists and Government.

— Continued

Table I
Comparative Prices of Some Essential Drugs

	<i>International Price per Kg</i>	<i>Rate in Indian Market per Kg</i>
Doxycyclin	1,337.00	5,890.00
Ethambutol	320.00	620.00
Frusemide	450.00	1,426.00
Gentamycin	3,500.00	35,670.00
Ampicillin	743.00	1,392.00

Table II
**Production of Some Essential Drugs
(In Metric Tonnes)**

	<i>1982-83 Production</i>	<i>Import</i>	<i>Requirement</i>
Dapsone	30.94	34.70	250
Vitamin A	52.49	20.45	150
Aspirin	1326.35	74.25	2000
Streptomycin	239.60	8.27	400
Chloroquine	80.82	198.25	500

Table III
Increase in Prices of Some Essential Drugs

	<i>1970 (Rs.)</i>	<i>1978 (Rs.)</i>	<i>1981 (Rs.)</i>
Streptomycin (1 gm)	0.65	1.37	2.61
INH PAS	7.80	14.45	24.00
Ethambutol (10 tabs)	—	9.45	11.50
Phenobarbitone (100 tabs)	—	3.00	10.00

10. MODEL LIST OF ESSENTIAL DRUGS

(Fourth Revision)

Explanatory Notes¹

Many drugs included in the list are preceded by a square symbol (☐) to indicate that they represent an *example of a therapeutic group* and that various drugs could serve as alternatives. It is imperative that this be understood when drugs are selected at national level, since choice is then influenced by the comparative cost and availability of equivalent products. Examples of acceptable substitutions include:

- ☐ Codeine: other drugs for the symptomatic treatment of diarrhoea such as diphenoxylate or loperamide or, when indicated for cough relief, noscapine or dextromethorphan.
- ☐ Hydrochlorothiazide: any other thiazide-type diuretic currently in broad clinical use.
- ☐ Hydralazine: any other peripheral vasodilator having an antihypertensive effect.
- ☐ Senna: any mild stimulant laxative (either synthetic or of plant origin).
- ☐ Sulfadimidine: any other short-acting systemically-active sulfonamide unlikely to cause crystalluria.

Numbers in parentheses following the drug names indicate:

- (1) Drugs subject to international control under (a) the Single Convention on Narcotic Drugs (1961), and (b) the Convention on Psychotropic Substances (1971);
- (2) Specific expertise, diagnostic precision, or special equipment required for proper use;
- (3) Greater potency or efficacy;
- (4) In renal insufficiency, contraindicated or dosage adjustments necessary;
- (5) To improve compliance;
- (6) Special pharmacokinetic properties for purpose;
- (7) Adverse effects diminish benefit/risk ratio;
- (8) Limited indications or narrow spectrum of activity;
- (9) For epidural anaesthesia.

Letters in parentheses following the drug names indicate the reasons for the inclusion of *complementary drugs*:

- (A) When drugs in the main list cannot be made available;
- (B) When drugs in the main list are known to be ineffective or inappropriate for a given individual;
- (C) For use in rare disorders or in exceptional circumstances.

¹ The numbers preceding the drug groups and subgroups in the model list (e.g. 11; 17.6.2) were allocated in accordance with English alphabetical order; they have no formal significance.

Main list	Complementary list	Route of administration, dosage forms, and strengths*
1. Anaesthetics		
1.1 General anaesthetics and oxygen		
ether, anaesthetic (2) ☐		inhalation
diazepam (1b, 2) ☐		injection, 5 mg/ml in 2-ml ampoule
halothane (2) ☐		inhalation
ketamine (2) ☐		injection, 50 mg/ml in 10-ml vial
nitrous oxide (2) ☐		inhalation
oxygen ☐		inhalation (medicinal gas)
thiopental (2) ☐		powder for injection, 0.5 g, 1.0 g (sodium salt) in ampoule
1.2 Local anaesthetics		
☐ bupivacaine (2, 9) ☐		injection, 0.25%, 0.5% (hydrochloride) in vial
☐ lidocaine ☐		injection, 1%, 2% (hydrochloride) in vial
		injection, 1%, 2% + epinephrine 1:100 000 in vial
		topical forms, 2-4% (hydrochloride)
2. Analgesics, Antipyretics, Nonsteroidal Antiinflammatory Drugs and Drugs Used to Treat Gout		
2.1 Non-opioids		
acetylsalicylic acid ☐		tablet, 100-500 mg
		suppository, 50-150 mg
allopurinol (4) ☐		tablet, 100 mg
☐ ibuprofen ☐		tablet, 200 mg
indometacin ☐		capsule or tablet, 25 mg
paracetamol ☐		tablet, 100-500 mg
		suppository, 100 mg
	☐ colchicine (8, c) (7)	tablet, 0.5 mg
	☐ probenecid (8, c)	tablet, 500 mg
2.2 Opioid analgesics		
codeine (1a) ☐		tablet, 30 mg (phosphate)
☐ morphine (1a) ☐		injection, 10 mg (sulfate or hydrochloride) in 1-ml ampoule
		oral solution, 10 mg in 5 ml
		tablet, 10 mg
	☐ pethidine (A) (1a, 4)	injection, 50 mg (hydrochloride) in 1-ml ampoule

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

Main list	Complementary list	Route of administration, dosage forms, and strengths*
3. Antiallergics		
☐ chlorphenamine ^B		tablet, 4 mg (maleate) injection, 10 mg in 1-ml ampoule
☐ dexamethasone ^C		tablet, 0.5 mg, 4 mg injection, 4 mg (sodium phosphate) in 1-ml ampoule
epinephrine ^C		injection, 1 mg (as hydrochloride) in 1-ml ampoule
☐ prednisolone ^C		tablet, 5 mg

4. Antidotes and Other Substances Used in Poisonings

4.1 General

charcoal, activated ^B	powder
ippecacuanha ^B	syrup, containing 0.14% ippecacuanha alkaloids calculated as emetine
☐ magnesium sulfate ^B	powder, 10–30 g

4.2 Specific

atropine ^B	injection, 1 mg (sulfate) in 1-ml ampoule
deferoxamine ^B	injection, 500 mg (mesilate) in vial
dimercaprol (2) ^B	injection in oil, 50 mg/ml in 2-ml ampoule
naloxone ^B	injection, 0.4 mg (hydrochloride) in 1-ml ampoule
sodium calcium edetate (2) ^B	injection, 200 mg/ml in 5-ml ampoule
sodium nitrite ^B	injection, 30 mg/ml in 10-ml ampoule
sodium thiosulfate ^B	injection, 250 mg/ml in 50-ml ampoule
methylthioninium chloride ^B	injection, 10 mg/ml in 10-ml ampoule
penicillamine (2) ^B	capsule or tablet, 250 mg

5. Antiepileptics

☐ diazepam (1b) ^B	injection, 5 mg/ml in 2-ml ampoule
ethosuximide ^C	capsule or tablet, 250 mg
phenobarbital (1b) ^C	tablet, 50 mg, 100 mg syrup, 15 mg/5 ml
phenytoin ^C	capsule or tablet, 25 mg, 100 mg (sodium salt) injection, 50 mg (sodium salt)/ml in 5-ml vial

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^BSynonym: methylene blue.

Main list	Complementary list	Route of administration, dosage forms, and strengths*
5. Antiepileptics (continued)		
	^C carbamazepine (a, c)	tablet, 200 mg
	^C valproic acid (a, c)	tablet, 200 mg (sodium salt) (2, 4, 7)

6. Antiinfective Drugs

6.1 Anthelmintic drugs

☐ mebendazole ^B	tablet, 100 mg
niclosamide ^B	tablet, 500 mg
piperazine ^B	tablet, 500 mg (citrate or adipate) elixir or syrup (as citrate) equivalent to 500 mg hydrate/5 ml
praziquantel ^B	tablet, 600 mg
pyrantel ^B	chewable tablet, 250 mg (as embonate) oral suspension, 50 mg (as embonate)/ml chewable tablet, 500 mg
tiabendazole ^B	

6.2 Antiamoebic drugs

chloroquine ^B	tablet, 200 mg (as phosphate or sulfate)
☐ diloxanide ^B	tablet, 500 mg (furoate)
☐ metronidazole ^B	tablet, 200–500 mg
	dehydroemetine (a) (7) injection, 60 mg (hydrochloride) in 1-ml ampoule

6.3 Antibacterial drugs

6.3.1 Penicillins

☐ ampicillin (4) ^C	capsule or tablet, 250 mg, 500 mg (anhydrous) powder for oral suspension, 125 mg (anhydrous)/5 ml powder for injection, 500 mg (as sodium salt) in vial
benzathine benzylpenicillin (5) ^C	injection, 1.44 g benzylpenicillin (= 2.4 million IU)/5 ml in vial
benzylpenicillin ^C	powder for injection, 0.6 g (= 1 million IU), 3.0 g (= 5 million IU) (as sodium or potassium salt) in vial
☐ cloxacillin ^C	capsule, 500 mg (as sodium salt) powder for injection, 500 mg (as sodium salt) in vial

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

Main list	Complementary list	Route of administration, dosage forms, and strengths.*
6. Antiinfective Drugs (continued)		
6.3 Antibacterial drugs (continued)		
6.3.1 Penicillins (continued)		
phenoxymethylpenicillin		tablet, 250 mg (as potassium salt) powder for oral suspension, 250 mg (as potassium salt)/5 ml
procaine benzylpenicillin		powder for injection, 1 g (= 1 million IU), 3 g (= 3 million IU)
6.3.2 Other antibacterial drugs		
□ chloramphenicol (7)		capsule, 250 mg powder for injection, 1 g (as sodium succinate) in vial oral suspension, 150 mg in 5 ml (as palmitate salt)
erythromycin		capsule or tablet, 250 mg (as stearate or ethyl succinate) oral suspension, 125 mg (as stearate or ethyl succinate)/5 ml powder for injection, 500 mg (as lactobionate) in vial injection, 10 mg, 40 mg (as sulfate)/ml in 2 ml vial tablet, 200–500 mg injection, 500 mg in 100 ml suppository, 500 mg; 1 g tablet, 500 mg powder for injection, 2 g (as hydrochloride) in vial tablet, 500 mg oral suspension, 500 mg/5 ml injection, 1 g (sodium salt) in 3-ml ampoule tablet, 100 mg + 20 mg, 400 mg + 80 mg
□ gentamicin (4)		
□ metronidazole		
salazosulfapyridine (2)		
spectinomycin (8)		
□ sulfadimidine (4)		
□ sulfamethoxazole + trimethoprim (4)		
□ tetracycline		
	doxycycline (a) (5, 6)	capsule or tablet, 100 mg (as hydrochloride) injection, 100 mg (as hydrochloride)/5 ml in ampoule
	nitrofurantoin (A, B) (4, 7)	tablet, 100 mg
6.3.3 Antileprosy drugs		
clofazimine		capsule, 50 mg, 100 mg
dapsone		tablet, 50 mg, 100 mg

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

Main list	Complementary list	Route of administration, dosage forms, and strengths*
6. Antiinfective Drugs (continued)		
6.3 Antibacterial drugs (continued)		
6.3.3 Antileprosy drugs (continued)		
rifampicin	ethionamide (a) protionamide (a)	capsule or tablet, 150 mg, 300 mg tablet, 125 mg, 250 mg tablet, 125 mg
6.3.4 Antituberculosis drugs		
ethambutol		tablet, 100–500 mg (hydrochloride) ^a
isoniazid		tablet, 100 mg–300 mg
pyrazinamide		tablet, 500 mg
rifampicin		capsule or tablet, 150 mg, 300 mg
streptomycin (4)		powder for injection, 1 g (as sulfate)/in vial
thioacetazone + isoniazid		tablet 50 mg + 100 mg, 150 mg + 300 mg
6.4 Antifilarial drugs		
diethylcarbamazine		tablet, 50 mg (citrate)
suramin sodium		powder for injection, 1 g in vial
6.5 Antifungal drugs		
amphotericin B (4)		powder for injection, 50 mg in vial
griseofulvin		tablet or capsule, 125 mg, 250 mg
nystatin		tablet, 500 000 IU pessary, 100 000 IU
	flucytosine (a) (4, 8)	capsule, 250 mg infusion, 2.5 g in 250 ml
6.6 Antileishmaniasis drugs		
pentamidine (5)		powder for injection, 200 mg (isetonate or mesilate) in vial
□ sodium stibogluconate		injection, 33%, equivalent to 10% antimony, in 30-ml vial
6.7 Antimalarial drugs		
□ chloroquine		tablet, 150 mg (as phosphate or sulfate) syrup, 50 mg (as phosphate or sulfate)/5 ml
primaquine		tablet, 7.5 mg, 15 mg (as phosphate)
quinine		tablet, 300 mg (as bisulfate or sulfate) injection, 300 mg (as dihydrochloride)/ml in 2-ml ampoule

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^aTwo strengths are required for individual dosage adjustment.

Main list	Complementary list	Route of administration, dosage forms, and strengths*
6. Antiinfective Drugs (continued)		
6.7 Antimalarial drugs (continued)		
	^B amodiaquine (a)	suspension, 150 mg (as hydrochloride)/5 ml tablet, 200 mg (as dihydrochloride dihydrate)
	^B sulfadoxine + pyrimethamine (a)	tablet, 500 mg + 25 mg
6.8 Antischistosomal drugs		
metritonate ^B		tablet, 100 mg
oxamniquine ^B		capsule, 250 mg syrup, 250 mg/5 ml tablet, 600 mg
praziquantel ^B		
6.9 Antitrypanosomal drugs		
melarsoprol (5) ^B		injection, 3.6% solution
pentamidine (5) ^B		powder for injection, 200 mg (isetonate or mesilate) in vial
suramin sodium ^B		powder for injection, 1 g in vial
	^B nifurtimox (c) (2, 8)	tablet, 30 mg, 120 mg, 250 mg

7. Antimigraine Drugs

ergotamine (7) ^C	tablet, 2 mg (as tartrate)
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8. Antineoplastic and Immunosuppressive Drugs

8.1 Immunosuppressive drugs

^B azathioprine (2) ^D	tablet, 50 mg powder for injection, 100 mg (as sodium salt) in vial
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8.2 Cytotoxic drugs

bleomycin (2) ^D	powder for injection, 15 mg (as sulfate) in vial
calcium folinate (2) ^B ^D	tablet, 15 mg injection, 3 mg/ml in 10-ml ampoule
cisplatin (2) ^D	powder for injection, 10 mg, 50 mg in vial
cyclophosphamide (2) ^D	tablet, 25 mg powder for injection, 500 mg in vial
cytarabine (2) ^D	powder for injection, 100 mg in vial
dactinomycin (2) ^D	powder for injection, 0.5 mg in vial
^B doxorubicin (2) ^D	powder for injection, 10 mg, 50 mg (hydrochloride) in vial

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^BDrug for "rescue therapy" with methotrexate.

Main list	Complementary list	Route of administration, dosage forms, and strengths*
8. Antineoplastic and Immunosuppressive Drugs (continued)		
8.2 Cytotoxic drugs (continued)		
etoposide (2) ^D		capsule, 100 mg injection 20 mg/ml in 5-ml ampoule injection, 50 mg/ml in 5-ml ampoule
fluorouracil (2) ^D		tablet, 50 mg
mercaptopurine (2) ^D		tablet, 2.5 mg (as sodium salt)
methotrexate (2) ^D		injection, 50 mg (as sodium salt) in vial
procarbazine ^D		capsule, 50 mg (as hydrochloride)
vinblastine (2) ^D		powder for injection, 10 mg in vial
vincristine (2) ^D		powder for injection, 1 mg, 5 mg (sulfate) in vial
8.3 Hormones and antihormones		
^B dexamethasone ^C		tablet, 0.5 mg, 4 mg injection, 4 mg (sodium phosphate) in 1-ml ampoule
^B prednisolone ^C		tablet, 5 mg injection, 20 mg, 25 mg (as sodium phosphate or succinate) in vial
tamoxifen ^C		tablet, 10 mg, 20 mg
9. Antiparkinsonism Drugs		
^B biperiden ^C		tablet, 2 mg (hydrochloride) injection, 5 mg (lactate) in 1-ml ampoule
levodopa + ^B carbidopa (5, 6) ^C		tablet, 100 mg + 10 mg, 250 mg + 25 mg
	levodopa (A)	tablet or capsule, 250 mg

10. Blood, Drugs affecting the

10.1 Antianaemia drugs

ferrous salt ^B	tablet, equivalent to 60 mg iron oral solution, equivalent to 15 mg iron (as sulfate) in 0.6 ml
ferrous salt + folic acid ^B	tablet, 60 mg + 200 µg
folic acid (2)	tablet, 1 mg injection, 1 mg (as sodium salt) in 1-ml ampoule
^B hydroxocobalamin (2) ^B	injection, 1 mg in 1-ml ampoule
	^B iron dextran (a) (5) ^C
	injection, equivalent to 50 mg iron/ml in 2-ml ampoule

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^BNutritional supplement for use during pregnancy.

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
10. Blood, Drugs affecting the (continued)		
10.2 Anticoagulants and antagonists		
heparin C		injection, 1000 IU/ml, 5000 IU/ml, 20 000 IU/ml in 1-ml ampoule
phytomenadione C		injection, 10 mg/ml in 5-ml ampoule
protamine sulfate C		injection, 10 mg/ml in 5-ml ampoule
warfarin (2, 6) C		tablet, 5 mg (sodium salt)

11. Blood Products and Blood Substitutes

11.1 Plasma substitute

dextran 70 C	injectable solution, 6%
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11.2 Plasma fractions for specific uses

albumin, human (2, 8) C	injectable solution, 25% (dried)	All plasma fractions should comply with the WHO Requirements for the Collection, Processing and Quality Control of Human Blood and Blood Products ^b
factor VIII concentrate (c) (2, 8) C		
factor IX complex (coagulation factors II, VII, IX, X) concentrate (c) (2, 8) C	(dried)	

12. Cardiovascular Drugs

12.1 Antianginal drugs

glyceryl trinitrate C	tablet, (sublingual) 0.5 mg
isosorbide dinitrate C	tablet, (sublingual) 5 mg
propranolol C	tablet, 10 mg, 40 mg (hydrochloride)
	injection, 1 mg (hydrochloride) in 1-ml ampoule
verapamil C	tablet, 40 mg, 80 mg (hydrochloride)
	injection, 2.5 mg/ml (hydrochloride) in 2-ml ampoule

12.2 Antidysrhythmic drugs

isoprenaline C	tablet, 10 mg, 15 mg (hydrochloride or sulfate)
lidocaine C	injection, 20 mg (hydrochloride)/ml in 5-ml ampoule
propranolol C	tablet, 10 mg, 40 mg (hydrochloride)
	injection, 1 mg (hydrochloride) in 1-ml ampoule

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bTwenty-seventh Report of the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 626, 1978, Annex 1).

Main list	Complementary list	Route of administration, dosage forms, and strengths ^a
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12. Cardiovascular Drugs (continued)

12.2 Antidysrhythmic drugs (continued)

quinidine C		tablet, 200 mg (sulfate)
	procainamide (a) C	tablet, 250 mg, 500 mg (hydrochloride)
		injection, 100 mg (hydrochloride)/ml in 10-ml ampoule

12.3 Antihypertensive drugs

hydralazine B		tablet, 50 mg (hydrochloride)
hydrochlorothiazide B		tablet, 50 mg
propranolol B		tablet, 40 mg, 80 mg (hydrochloride)
sodium nitroprusside (2, 8) C		powder for preparing infusion, 50 g in ampoule
reserpine B		tablet, 0.1 mg, 0.25 mg
		injection, 1 mg in 1-ml ampoule
	methyldopa (A, B) (7) B	tablet, 250 mg

12.4 Cardiac glycosides

digoxin (4) C		tablet, 0.0625 mg, 0.25 mg
		oral solution, 0.05 mg/ml
		injection, 0.25 mg/ml in 2-ml ampoule
	digitoxin (a) (6) C	tablet, 0.05 mg, 0.1 mg
		oral solution, 1 mg/ml
		injection, 0.2 mg in 1-ml ampoule

12.5 Drugs used in shock or anaphylaxis

dopamine B C		injection, 40 mg (hydrochloride)/ml in 5-ml vial
epinephrine B C		injection, 1 mg (as hydrochloride) in 1-ml ampoule

13. Dermatological Drugs

13.1 Antifungal drugs

benzoic acid + salicylic acid A		ointment or cream, 6% + 3%
miconazole B		ointment or cream, 2% (nitrate)
nystatin B		ointment or cream, 100 000 IU/g

13.2 Antiinfective drugs

gentian violet ^b A		aqueous or alcoholic solution, 1%
neomycin + bacitracin B		ointment, 5 mg neomycin sulfate + 500 IU bacitracin zinc/g

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bAlso known as crystal violet (International Nonproprietary Name: methylosanilinium chloride).

Main list	Complementary list	Route of administration, dosage forms, and strengths*
13. Dermatological Drugs (continued)		
13.3 Antinflammatory and antipruritic drugs		
☐ betamethasone (3)		ointment or cream, 0.1% (as valerate)
☐ calamine lotion		lotion
☐ hydrocortisone		ointment or cream, 1% (acetate)
13.4 Astringent drugs		
aluminium acetate		solution, 13% for dilution
13.5 Keratoplastic and keratolytic agents		
coal tar		solution, topical 20%
podophylline		solution, 10-25%
salicylic acid		solution, topical 5%
13.6 Scabicides and pediculicides		
benzyl benzoate		lotion, 25%
lindane ^b		cream or lotion, 1%
14. Diagnostic Agents		
14.1 Ophthalmic drugs		
fluorescein		eye drops, 1% (sodium salt)
14.2 Radiocontrast media		
☐ meglumine amidotrizoate		injection, 60% in 20-ml ampoule
☐ sodium amidotrizoate		injection, 50% in 20-ml ampoule
barium sulfate		powder
☐ iopanoic acid		tablet, 500 mg
☐ propyl iodone		injection, 600 g/l in 20-ml ampoule
	☐ iohexol (c)	injection, 300 mg in 5- or 10-ml ampoule
	☐ iotroxate (c)	solution, 8 g (as iodine) in 100 to 250 ml
15. Disinfectants		
☐ chlorhexidine		solution, 5% (digluconate) for dilution
☐ iodine		solution, 2.5%
	gentian violet ^c (A)	topical solution, 1%

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bPreviously identified as gamma benzene hexachloride.

^cAlso known as crystal violet (International Nonproprietary Name: methylrosanilinium chloride).

Main list	Complementary list	Route of administration, dosage forms, and strengths*
16. Diuretics		
☐ amiloride		tablet, 5 mg (hydrochloride)
☐ furosemide		tablet, 40 mg
		injection, 10 mg/ml in 2-ml ampoule
☐ hydrochlorothiazide		tablet, 50 mg
mannitol		injectable solution, 10%, 20%
spironolactone		tablet, 25 mg
	chlortalidone (e) (6)	tablet, 25 mg
17. Gastrointestinal Drugs		
17.1 Antacids and other antilucer drugs		
aluminium hydroxide		tablet, 500 mg
		oral suspension, 320 mg/5 ml
☐ cimetidine		tablet, 200 mg
		injection, 200 mg in 2-ml ampoule
magnesium hydroxide		oral suspension, equivalent to 550 mg magnesium oxide/10 ml
	calcium carbonate (A, B)	tablet, 600 mg
17.2 Antiemetic drugs		
☐ promethazine		tablet, 10 mg, 25 mg (hydrochloride)
		elixir or syrup, 5 mg (hydrochloride)/5 ml
		injection, 25 mg (hydrochloride)/ml in 2-ml ampoule
metoclopramide		tablet, 10 mg (as hydrochloride)
		injection, 5 mg/ml in 2-ml ampoule
17.3 Antihæmorrhoidal drugs		
☐ local anaesthetic, astringent and antiinflammatory drug		ointment or suppository
17.4 Antispasmodic drugs		
☐ atropine		tablet, 1 mg (sulfate)
		injection, 1 mg (sulfate) in 1-ml ampoule
17.5 Cathartic drugs		
☐ senna		tablet, 7.5 mg (sennosides) (or traditional dosage forms)
17.6 Diarrhoea, Drugs used in		
17.6.1 Antidiarrhoeal (symptomatic) drugs		
☐ codeine (1a)		tablet, 30 mg (phosphate)

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

Main list	Complementary list	Route of administration, dosage forms, and strengths*
17. Gastrointestinal Drugs (continued)		
17.6 Diarrhoea, Drugs used in (continued)		
17.6.2 Replacement solution		
oral rehydration salts		
(for glucose-salt solution)		
	g/litre	
sodium chloride	3.5	} B
trisodium citrate dihydrate ^b	2.9	
potassium chloride	1.5	
glucose	20.0	

18. Hormones**18.1 Adrenal hormones and synthetic substitutes**

☐ dexamethasone		tablet, 0.5 mg, 4 mg injection, 4 mg (sodium phosphate) in 1-ml ampoule
hydrocortisone		powder for injection, 100 mg (as sodium succinate) in vial
☐ prednisolone		tablet, 5 mg
	fludrocortisone (c)	tablet, 0.1 mg (acetate)

18.2 Androgens

testosterone (2)		injection, 200 mg (enantate) in 1-ml ampoule injection, 25 mg (propionate) in 1-ml ampoule
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18.3 Contraceptives

☐ ethinylestradiol + ☐ levonorgestrel		tablet, 0.03 mg + 0.15 mg, 0.05 mg + 0.25 mg
☐ ethinylestradiol + ☐ norethisterone		tablet, 0.05 mg + 1.0 mg
	depot medroxy-progesterone acetate (s) (7, 8)	injection, 150 mg in 3-ml vials
	☐ norethisterone (s)	tablet, 0.35 mg
	norethisterone enantate (s) (7, 8)	injection, 200 mg in vial

18.4 Estrogens

☐ ethinylestradiol		tablet, 0.05 mg
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*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bMay be replaced by sodium bicarbonate (sodium hydrogen carbonate), 2.5 g/litre, when citrate salt is not available.

Main list	Complementary list	Route of administration, dosage forms, and strengths*
18. Hormones (continued)		
18.5 Insulins and other antidiabetic agents		
insulin injection (soluble)	C	injection, 40 IU/ml in 10-ml vial, 80 IU/ml in 10-ml vial
intermediate acting insulin	C	injection, 40 IU/ml in 10-ml vial, 80 IU/ml in 10-ml vial (as compound insulin zinc suspension or isophane insulin)
glibenclamide	B	tablet, 5 mg
18.6 Ovulation inducers		
	☐ clomifene (c) (2, 8)	tablet, 50 mg (citrate)
18.7 Progestogens		
norethisterone	C	tablet, 5 mg
18.8 Thyroid hormones and antithyroid drugs		
levothyroxine	C	tablet, 0.05 mg, 0.1 mg (sodium salt)
potassium iodide	B	tablet, 60 mg
☐ propylthiouracil	B	tablet, 50 mg
19. Immunologicals		
19.1 Diagnostic agents		
tuberculin, purified protein derivative (PPD)	C	injection
19.2 Sera and immunoglobulins		
anti-D immunoglobulin (human)	C	injection, 0.25 mg/ml
antirabies hyperimmune serum	C	injection, 1000 IU in 5-ml ampoule
antivenom sera	C	injection
antiscorpion sera	C	injection
diphtheria antitoxin	C	injection, 10 000 IU, 20 000 IU, in vial
immunoglobulin, human normal (2)	C	injection
tetanus antitoxin	C	injection, 50 000 IU, in vial
tetanus antitoxin (human)	C	injection, 500 IU in vial

All plasma fractions should comply with the WHO Requirements for the Collection, Processing, and Quality Control of Human Blood and Blood Products^b

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bWHO Technical Report Series, No. 626, 1978, Annex 1.

Main list	Complementary list	Route of administration, dosage forms, and strengths*
19. Immunologicals (continued)		
19.3 Vaccines		
19.3.1 For universal immunization		
BCG vaccine (dried)		injection
diphtheria-pertussis-tetanus vaccine		injection
diphtheria-tetanus vaccine		injection
measles vaccine		injection
poliomyelitis vaccine (inactivated)		injection
poliomyelitis vaccine (live attenuated)		oral solution
tetanus vaccine		injection
		All vaccines should comply with the WHO Requirements for Biological Substances ^b
19.3.2 For specific groups of individuals		
influenza vaccine		injection
meningococcal vaccine		injection
rabies vaccine		injection
typhoid vaccine		injection
yellow fever vaccine		injection

20. Muscle Relaxants (Peripherally Acting) and Cholinesterase Inhibitors

☐ gallamine (2)		injection, 40 mg (triethiodide)/ml in 2-ml ampoule
☐ neostigmine		tablet, 15 mg (bromide)
		injection, 0.5 mg (metilsulfate) in 1-ml ampoule
suxamethonium (2)		injection, 50 mg (chloride)/ml in 2-ml ampoule
	pyridostigmine (a) (2, 8)	tablet, 60 mg (bromide)
		injection, 1 mg (bromide) in 1-ml ampoule

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bDried BCG Vaccine (Revised 1978) (WHO Technical Report Series, No. 638, 1979); Diphtheria Toxoid, Pertussis Vaccine, Tetanus Toxoid, and Combined Vaccines (Revised 1978) (WHO Technical Report Series, No. 638, 1979), Addendum 1983 (WHO Technical Report Series, No. 700, 1984, and Addendum 1984 (WHO Technical Report Series, No. 725, 1985); Measles Vaccine (Live) and Measles Vaccine (Inactivated) (WHO Technical Report Series, No. 329, 1966); Poliomyelitis Vaccine (Oral) (Revised 1982) (WHO Technical Report Series, No. 687, 1983); Poliomyelitis Vaccine (Inactivated) (Revised 1981) (WHO Technical Report Series, No. 673, 1982; Influenza Vaccine (Inactivated) (Revised 1978) (WHO Technical Report Series, No. 638, 1979); Meningococcal Polysaccharide Vaccine (WHO Technical Report Series, No. 658, 1981), Addendum 1980, incorporating Addendum 1976 (WHO Technical Series, No. 658, 1981); Rabies Vaccine for Human Use (Revised 1980) (WHO Technical Report Series, No. 658, 1981); Typhoid Vaccine (Live Attenuated, Ty 21a, Oral) (WHO Technical Report Series, No. 700, 1984); Yellow Fever Vaccine (Revised 1975) (WHO Technical Report Series, No. 594, 1976).

Main list	Complementary list	Route of administration, dosage forms, and strengths*
21. Ophthalmological Preparations		
21.1 Antilfective agents		
silver nitrate	B	solution (eye drops), 1%
sulfacetamide	B	eye ointment, 10% (sodium salt)
		solution (eye drops), 10% (sodium salt)
☐ tetracycline	B	eye ointment, 1% (hydrochloride)
21.2 Antiinflammatory agents		
☐ hydrocortisone (2, 7)	C	eye ointment, 1% (acetate)
21.3 Local anaesthetics		
☐ tetracaine	B	solution (eye drops), 0.5% (hydrochloride)
21.4 Miotics and antiglaucoma drugs		
acetazolamide		tablet, 250 mg
☐ pilocarpine	B	solution (eye drops), 2%, 4% (hydrochloride or nitrate)
☐ timolol	B	solution (eye drops), 0.25%, 0.5% (maleate)
21.5 Mydriatics		
☐ homatropine	B	solution (eye drops), 2% (hydrobromide)
	epinephrine (A, B)	solution (eye drops), 2% (as hydrochloride)
22. Oxytocics		
☐ ergometrine	C	tablet, 0.2 mg (maleate)
		injection, 0.2 mg (maleate) in 1-ml ampoule
oxytocin	C	injection, 10 IU in 1-ml ampoule
23. Peritoneal Dialysis Solution		
intraperitoneal dialysis solution (of appropriate composition)	C	parenteral solution
24. Psychotherapeutic Drugs		
☐ amitriptyline	C	tablet, 25 mg (hydrochloride)
☐ chlorpromazine	C	tablet, 100 mg (hydrochloride)
		syrup, 25 mg (hydrochloride)/5 ml
		injection, 25 mg (hydrochloride)/ml in 2-ml ampoule

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

Main list	Complementary list	Route of administration, dosage forms, and strengths*
24. Psychotherapeutic Drugs (continued)		
☐ diazepam (1b)		tablet, 5 mg
☐ fluphenazine (5)		injection, 25 mg (decanoate or enantate) in 1-ml ampoule
☐ haloperidol		tablet, 2 mg
		injection, 5 mg in 1-ml ampoule
imipramine		tablet, 10 mg, 25 mg (hydrochloride)
lithium carbonate (2, 4)		capsule or tablet, 300 mg

25. Respiratory Tract, Drugs acting on the

25.1 Antilasthmatic drugs

☐ aminophylline (2)		tablet, 100 mg, 200 mg
		injection, 25 mg/ml in 10-ml ampoule
epinephrine		injection, 1 mg (as hydrochloride) in 1-ml ampoule
☐ salbutamol		tablet, 4 mg (sulfate)
		oral inhalation (aerosol), 0.1 mg (sulfate) per dose
		syrup, 2 mg (sulfate)/5 ml
		injection, 50 µg/ml in 5-ml ampoule
	beclomethasone (b)	oral inhalation (aerosol), 0.05 mg (dipropionate) per dose
	cromoglicic acid (b)	oral inhalation (cartridge), 20 mg (sodium salt) per dose
		tablet, 30 mg (as hydrochloride)
ephedrine		elixir, 15 mg (as hydrochloride)/5 ml
		injection, 50 mg (sulfate) in 1-ml ampoule

25.2 Antitussives

☐ codeine (1a)	tablet, 10 mg (phosphate)
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26. Solutions Correcting Water, Electrolyte, and Acid-Base Disturbances

26.1 Oral

oral rehydration salts (for glucose-salt solution)	For composition see 17.6.2
potassium chloride	Replacement solution
	oral solution

26.2 Parenteral

☐ compound solution of sodium lactate	injectable solution
glucose	injectable solution, 5% isotonic, 50% hypertonic

*When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

Main list	Complementary list	Route of administration, dosage forms, and strengths*
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26. Solutions Correcting Water, Electrolyte, and Acid-Base Disturbances (continued)

26.2 Parenteral (continued)

glucose with sodium chloride	injectable solution, 4% glucose, 0.18% sodium chloride (Na ⁺ 30 mmol, Cl ⁻ 30 mmol/l)
potassium chloride	injectable solution
sodium bicarbonate	injectable solution, 1.4% isotonic (Na ⁺ 167 mmol/l, HCO ₃ ⁻ 167 mmol/l); 8.4% solution in 10-ml ampoule
sodium chloride	injectable solution, 0.9% isotonic (Na ⁺ 154 mmol/l, Cl ⁻ 154 mmol/l)

26.3 Miscellaneous

water for injection	in 2-ml, 5-ml, 10-ml ampoules
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27. Vitamins and Minerals

ascorbic acid	tablet, 50 mg
☐ ergocalciferol	capsule or tablet, 1.25 mg (50 000 IU)
	oral solution, 0.25 mg/ml (10 000 IU)
☐ nicotinamide	tablet, 50 mg
pyridoxine	tablet, 25 mg (hydrochloride)
retinol	capsule or tablet, 7.5 mg (25 000 IU)
	60 mg (200 000 IU) ^b
	oral solution, 15 mg/ml (50 000 IU)
riboflavin	tablet, 5 mg
sodium fluoride (8)	tablet, 0.5 mg (as fluoride)
thiamine	tablet, 50 mg (hydrochloride)
	injection, 100 mg/ml in 10-ml ampoule
	calcium gluconate (c), (2, 8)

^aWhen the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

^bFor use in the treatment and prophylaxis of xerophthalmia.

The New Drug Policy Statement — A Critique

The New Drug Policy Statement issued by the Government on 18 December, 1986 has come as an unpleasant surprise to many. It is obvious from the statement that the Government has totally capitulated to the unreasonable demands of the Pharmaceuticals Industry. The Government has rushed through piecemeal changes in the 1978 Policy while many important issues have been kept in abeyance. The changes articulated in the policy statement pertain only to Pricing and Licensing. The shifts in these areas are in accordance with the demands being made by the industry, while the interests of the consumers and the indigenous sector have been totally ignored. It is all the more surprising that this Policy has been announced barely a week after adjournment of the Parliament. This is a blatant attempt at by-passing the people's representatives. One had expected that such an important Policy, which will have far reaching impact on the Health of millions, would have been debated thoroughly before being finalised.

Pricing :

The New Policy shall have an escalatory effect on prices of Drugs. According to the new policy, the number of Drugs under Price Control has been reduced (from three to two categories) and the Mark-up allowed on controlled categories increased (to 75% and 100% from 40% and 55%, respectively). Thus the number of Drugs whose prices are to be controlled has been reduced while the profitability on price-controlled drugs has been increased. Such a change is likely to increase the cost of therapy by 50 – 200 per cent. The impact of such a steep rise in prices shall be catastrophic.

This increase in prices has been recommended in the absence of any unbiased study on the profitability of Drugs. The study used by the government in the area of pricing was done by the National Council of Applied Economic Research (NCAER). But this study was sponsored and financed by the OPPI (the organisation of Foreign Companies in the Pharmaceutical Industry). Further, the Drugs which shall now be price-controlled will presumably be essential drugs. As MNCs produce very few essential drugs, the new pricing structure will ensure that most of the drugs manufactured by them shall be outside the pale of price control.

It also needs to be noted that while the pricing structure has been announced, the final list of drugs to be included in the price-controlled categories is yet to be drawn up. This will allow intensive lobbying, manipulations and even downright corruption by various manufacturers, in order to keep their products out of the price-controlled categories.

Licensing :

The new policy has enlarged the scope of the delicensing scheme. The new scheme of delicensing would be extended to all the bulk drugs whose imports are allowed on open general license. Further, in the case of all new bulk drugs and related formulations developed in the country the scheme of delicensing would now be available to all drug firms, including FERA companies.

This scheme of delicensing shall increase the country's dependence on imports. It will encourage the international companies to abandon the production of essential drugs from the basic stages. They will now have full freedom to increase production of their formulations, based on imported bulk drugs. Increased imports of *Ibuprofen*, *Beta Methazone*, *Hydrocortisone*, *Chloramphenicol* and *Pseudoephedrine* by the international companies are clear examples of what would be the negative impact of the scheme of delicensing when it would be extended to all the bulk drugs whose imports are allowed on open general license. For the extent of increased import of bulk drugs by international companies, see Appendix - I.

The new expanded scheme of delicensing will create a state of anarchy in the industry. Evidence of this kind of anarchy can already be seen in the fact that for most of the delicensed drugs (the government introduced the scheme of delicensing for 12 bulk drugs in March, 1983 and extended it to 82 more bulk drugs in June, 1985), there was a severe fall in production. In most of the cases they are being produced much below the installed capacity of 1983. A list of delicensed drugs whose production has been on the decline is at Appendix - II.

The scheme of delicensing will even destroy what has already been achieved towards self-reliance in the production of drugs. The present list of 94 delicensed drugs includes many for which the Indian Sector has the capability and adequate capacity to ensure adequate production. This includes drugs like *Ampicillin*, *Chloramphenicol*, *Chloroquine*, *Diazepam*, *Metronidazole*, *Erythromycin*, *Propanolol* etc. Further delicensing will adversely affect the Indian manufacturers. The step of delicensing is thus against one of the principal aims of our Industrial Policy i.e., attainment of self-reliance. A list of delicensed drugs for which the Indian Sector has developed complete, capability for the production of bulk drugs and formulations is at Appendix - III.

Previous Recommendations Ignored :

The thrust of the new policy is aimed at dilution of the objectives set out by the Hathi Committee in 1974 and virtual abandonment of the 1978 Drug Policy. The new Policy appears to believe that opening the doors to MNCs shall ensure increased production and entry of new technology. The Hathi Committee had clearly reported that MNCs are not interested in producing essential bulk drugs or in bringing in new technology. In the intervening period there has been no evidence that MNCs have changed their attitude since then. One is hence unable to understand this shift in government Policy.

The 1978 Drug Policy had many commendable provisions. Unfortunately most of them were never implemented viz.,

- Of the total turnover of each manufacturer, 20% must be made up by essential drugs.
- Equity dilution by Foreign companies shall be done by block purchase of shares by Public Finance Institutions.
- For those engaged in manufacture from imported raw materials and penultimate, manufacture from basic stage shall be ensured in two years.
- Many of the Price Control mechanisms were blocked by the manufacturers through Court injunctions.
- Profitability ceiling of 12 — 14% post tax returns for individual manufacturers.
- Stipulation that a certain percentage of turnover be spent on R&D.

One fails to understand why the Drug Policy of 1978 is being given a silent burial when many of its provisions (as cited above) were not implemented at all.

National Drugs and Therapeutics Authority (NDTA)

The proposal to set up a NDTA is in itself a welcome step. But it has been proposed that it will only be an Advisory body without statutory powers. Such a body cannot be effective in monitoring the functioning of the Pharmaceuticals Industry.

Further, for the NDTA to be really representative in character, representation must be given to organisations of Doctors, Medical Representatives, Trade Unions and Consumer Groups. It must also include representatives from different States. In the absence of this, the NDTA as presently envisaged, shall prove to be an ineffective and useless body.

Health Aspects Ignored :

The new Policy is ominously silent about the Health aspects of the Drug Policy. No National Drug Policy can have its foundations in pricing and

licensing policies. It is evident that the Health authorities have not even been consulted before formulation of the Policy. Thus nothing concrete has been said about the phasing out of hazardous drugs and irrational formulations. No attempt has been made to formulate an Essential Drug list. Thus while the government has moved with alacrity to satisfy the Industry lobby, the Health of the people has been totally ignored.

Recommendations :

The new Policy marks a major shift in the government's Policy in favour of the Industry, especially the Foreign Sector. The New Drug Policy must take into account the following points :

1. No drug should be kept out of the pale of price control.
2. Before changing the pricing structure of drugs, an independent study (preferably by the Bureau of Industrial Costs and Pricing) should be undertaken.
3. The NDTA should be formed as a truly representative body with statutory powers.
4. The policy of delicensing should be abandoned and the system of sectoral reservations should continue.
5. Before the list of drugs for price control is formulated, a graded list of essential drugs should be prepared and irrational formulations to be weeded out must be identified.
6. Hazardous drugs which are to be banned should be identified.
7. The Public Sector should be encouraged to play a leading role in the Pharmaceuticals Industry.
8. The Drug Policy should not be clandestinely brought in by piecemeal formulations. It should be prepared in a comprehensive manner taking all the above aspects into consideration. Before its formal adoption it should be discussed extensively at all levels. □

Import of Bulk Drugs and Their Production by TNCs

	Unit	1980-81	1981-82	1982-83	1983-84	1984-85	TNC
Ibuprofen							
Import (OGL)	MT	4	13	25	37	62	Boots
Production		20	19	28	43	51	
Hydrocortisone							
Import (OGL)	KG	20	629	794	577	775	John Wyeth
Production	KG	N.A.	N.A.	106	124	52	
Sulphamethoxazole							
Import (OGL)	MT	133	1	2	4	20	Roche & other Indian Cos
Chloramphenicol (L-base)							
Import (OGL)	MT	121	118	99	117	121	B. Knoll & Parke Davis
Production		128	148	111	97	130	
Cephalexin							
Import (OGL)	MT	1	2	10	18	36	Glaxo
Production		Nil	Nil	Nil	Nil	Nil	
Ephedrine							
Import (OGL)	MT	17	20	44	36	37	B. Knoll
Production		22	12	2	2	6	
Pseudoephedrine							
Import (OGL)	MU	N.A.	6481	4900	13982	9855	B Wellcome
Production		N.A.	N.A.	0.1	Nil	Nil	
Dapsone							
Import (Canalised)	MT	0.3	19	35	13	8	B. Wellcome
Production		22	26	31	29	7	

Source : Drugs Statistics of India 1985-86

Decline in Production of Delicensed Drugs
(Monitored bulk drugs)

Drug	Unit	1983-84	1984-85	1985-86
Chloramphenicol	T	52.03	78.53	55.18
Ampicillin	T	56.44	104.69	74.79
Sulphamethoxazole	T	375.94	539.08	360.00
Vitamin C	T	843.26	715.23	388.72
Aspirin	T	1526.38	1061.33	854.91
Pyrazinamide	T	5.49	2.62	1.90
PAS & its salts	T	216.99	119.07	55.09
Chloroquin	T	122.58	147.39	109.01
Amodiaquin	T	117.77	151.10	85.59
Metronidazole	T	215.81	295.07	221.70
Tolbutamide	T	24.06	28.76	11.15
Glybenclamide	Kgs	1.05	0.97	0.53
Methyldopa	T	10.93	19.04	15.46
Procaine	Kgs	70.16	32.40	9.29
Diazepam	T	3.42	5.73	3.23
Dapsone	T	29.27	7.25	4.89
Trimethoprim	T	61.31	46.53	30.60

Source : Chemical Weekly, Annual Number, 1986

Delicensed Drugs Where Indian Sector Has
Complete Production Capabilities :

- | | |
|-------------------------|-----------------------|
| 1. Ampicillin | 12. Frusemide |
| 2. Chloramphenicol | 13. Glybenclamide |
| 3. Chlorpropamide | 14. Ibuprofen |
| 4. Chloroquin phosphate | 15. Mebendazole |
| 5. Clofazimine | 16. Metronidazole |
| 6. Dexamethasone | 17. Norethisterone |
| 7. Diazepam | 18. Propranolol |
| 8. Dexycycline | 19. Pyrazinamide |
| 9. Erythromycin | 20. Sulphamethoxazole |
| 10. Ethambutol | 21. Trimethoprim |
| 11. Ethinyl Estradiol | 22. Gryseofulvin |

Drug Industry and The Indian People

This unique publication contains selected papers presented at the All India Seminar on National Drug Policy, held at New Delhi on 28th and 29th April, 1986

The Seminar was co-sponsored by the following organisations :

- Delhi Science Forum (DSF)
- Federation of Medical Representatives' Associations of India (FMRAI)
- All India Chemical and Pharmaceutical Employees Federation (AICAPEF)
- Kerala Shastra Sahitya Parishad (KSSP)
- Confederation of Doctors' Associations, Maharashtra (CODA)
- Madhya Pradesh Vigyan Sabha (MPVS)

This book brings together for the first time, analytical studies of all aspects of the Drug Industry in an integrated form. In addition, many associated materials viz., WHO List of Essential Drugs, Bangladesh Drug Policy, excerpts from Hathi Committee Report etc., are reproduced. A critique of the New Drug Policy Statement issued by the Government of India on 18 December, 1986 is also included.

We believe the book will be a valuable document in the hands of all those who are involved in the fields of Health and Pharmaceuticals.